IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS CORPORATION, ----------Plaintiff, vs. LIQUIDIA TECHNOLOGIES, INC., ----------Defendant.	) Case No. 23-CV-975-RGA) Volume IV

TRANSCRIPT OF BENCH TRIAL

BENCH TRIAL had before the Honorable Richard G. Andrews, U.S.D.C.J., in Courtroom 6A on the 26th of June, 2025.

APPEARANCES

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-and-

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(Appearances continued.)

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Counsel for Defendant

THE COURT: All right. Good morning. And I believe we have -- Dr. Nathan, be seated -- Dr. Nathan on the stand.

And, Mr. Davies, I guess you were going to cross-examine him?

MR. DAVIES: I am, Your Honor. Thank you.

May I proceed, Your Honor?

THE COURT: Yes.

CROSS-EXAMINATION

BY MR. DAVIES:

Q. Good morning, Dr. Nathan.

A. Good morning.

Q. You don't dispute that Tyvaso was sold beginning in 2009; correct?

A. I do not.

Q. And it's just that in your opinion, prior to April 2020, there was not an off-label sale of Tyvaso; correct?

A. That's correct.

Q. So you're saying doctors did not write off-label prescriptions of Tyvaso in PH-ILD; is that right?

A. I didn't say that.

Q. Okay. Yesterday you said prescriptions are confidential, so you can't actually say what other physicians wrote in their prescriptions; correct?

A. That's correct.
Q. And it's your opinion that prior to April 2020, doctors could not write off-label prescriptions for Tyvaso because they couldn't have intended to improve exercise capacity without the results of the INCREASE trial; is that correct?
A. That's correct.
Q. And so your prior sale opinions, you believe that it has to be UTC that directly makes those sales; right?
A. Yes.
Q. And in your opinion, the prior sale -- and in your analysis, that prior sale had to be a public prior sale; correct?
A. Yes.
Q. Okay. You heard testimony about Dr. Rothblatt's statements to investors that insurance companies paid for Tyvaso for PH-ILD patients off label; correct?
A. Yes.
Q. But you don't believe Dr. Rothblatt's statements; right?
A. I believe that's what Dr. Rothblatt said.
Q. But that didn't impact your opinion that there were no prior off-label sales of Tyvaso for PH-ILD prior to April 2020 that were reimbursed by insurance companies; right?

A. The sales were for PAH, and how the physician used it was at the discretion of the physician.
Q. You didn't review any sales records in this case, did you?
A. I don't know.
Q. So you don't know what the sales were made for; correct?
A. I do know they were made for PAH because in order to get PAH paid for, physicians have to attest on the form that the patients have pulmonary arterial hypertension.
Q. You heard Dr. Hill and Dr. Saggar say that insurance companies rejected their prescriptions for Tyvaso when they wrote them for PH-ILD; correct?
A. I heard Dr. Hill say that, yeah.
Q. Okay. And you heard that in some cases they were rejected even when they checked the box for diagnosing with PAH; correct?
A. I did.
Q. But you still believe that Tyvaso was never sold to a patient for PH-ILD before April of 2020; correct?
A. Yes.
Q. In terms of how you treated the claims in your opinions on obviousness, you believe that the '327 patent claims would only be met if a physician knew that Tyvaso actually produced an improvement in exercise capacity in

that PH-ILD patient; correct?

A. Correct.

Q. And it's your opinion, also in the context of your obviousness opinions, that a physician could not have known what Tyvaso would do in a PH-ILD patient before the results of the INCREASE study were unblinded; right?

A. That's correct.

Q. Okay. I'd like to talk a little bit about dry powders.

You talked yesterday that nobody would know how to make a dry powder formulation of treprostinil; right?

A. A POSA would not know how to do that; correct.

MR. DAVIES: Can we look at the '327 patent. And can we look at column 21, lines 6 through 14.

BY MR. DAVIES:

Q. And you see here, Doctor, that this portion of the '327 patent identifies both dry powder and a dry powder inhaler, composition of treprostinil; correct?

A. Yes.

Q. It says that these formulations were already disclosed in 20- -- in the WO/2019/237028 publication; correct?

A. I'm not sure which publication that is.

Q. But you see that it says that these prior art dry powder inhalers and dry powder compositions of treprostinil

were already disclosed in WO/2019/237028; correct?

A. I see that.

MR. DAVIES: Can we go to column --

THE COURT: Sorry, Mr. Davies.

MR. DAVIES: Yes.

THE COURT: So when you said a POSA wouldn't know how to make a dry powder formulation, is that because the POSA you're thinking about is a medical doctor?

THE WITNESS: Yes.

THE COURT: So if the medical doctor was working with a doctor of pharmacy, do you have an opinion as to whether a doctor of pharmacy would know how to do this?

THE WITNESS: I really don't think so. I think it takes a whole team to develop a dry powder inhaler. So this wouldn't be a pharmacist by themselves in terms of formulating the molecule and then coming up with a device to deliver that, the dry powder. So it really takes a team.

THE COURT: All right. Thank you.

MR. DAVIES: Can we go -- stay in the '327 patent, and can we go to column 15, lines 1 to 10.

BY MR. DAVIES:

Q. And do you see here, Doctor, this is another discussion in the specification of the '327 patent about treprostinil dry powder compositions and inhalable compositions? Do you see that?

A. Yes.
Q. Okay. And here it says that those compositions were previously described in U.S. Patent Number 9,339,507; correct?
A. It says that, yes.
MR. DAVIES: Okay. Rob, can we go to the '793 patent and look at the related application data.
BY MR. DAVIES:
Q. And, Doctor, you offered opinions of -- sorry.
MR. JACKSON: The DTX number?
MR. DAVIES: DTX 2.
BY MR. DAVIES:
Q. And, Doctor, you offered opinions about the '793 patent in this case; correct?
A. I did.
Q. And if we look at the U.S. application data --
MR. DAVIES: Rob, can you blow that up. And you can see the U.S. Patent Number 9,339,507 that's cited there. Can you highlight that, Rob? It's about six lines down on the left. Yep.
BY MR. DAVIES:
Q. And so you see that the '507 patent is actually in the same patent family as the '793 patent and cited on the face of the '793 patent; correct?
A. I see it's cited there.

Q. You're just not sure if it's in the same family because you're not an attorney; right?
A. Yeah, I haven't seen that patent and so I'm not sure what's in that patent.
Q. Totally understood.
MR. DAVIES: Can we look at back at the '327 patent. And let's look at column 20, lines 48 to 57.
BY MR. DAVIES:
Q. And this is another disclosure in the '327 patent that's concerning dry powder compositions of treprostinil and dry powder inhalers using treprostinil; correct?
A. I'm just reading it.
Q. Yeah, no problem.
A. Yeah.
Q. And do you see here that both the '507 patent that we've already looked at and also the '793 patent that you've offered opinions on in this case are both cited and incorporated here by reference for that description of dry powder inhalers and dry powder compositions of treprostinil; correct?
A. You said that I looked at the '507 patent. I haven't seen that patent.
Q. I'm sorry.
You looked at the '793 patent; right?
A. Correct.

Q. But you believe at least here in the '327, both of those, it says they're being incorporated herein in their entirety for the disclosure of dry powder inhalers and dry powder compositions of treprostinil; correct?

A. Correct.

MR. DAVIES: Rob, can we please pull up DTX 62.

BY MR. DAVIES:

Q. And, Dr. Nathan, we've just been talking about the '507 patent.

And you can see this is U.S. Patent Number 9,339,507 issued by the United States Patent Office; correct?

A. I see that, yes.

Q. And the date of this patent is May 17, 2016?

A. Correct.

MR. DAVIES: Your Honor, I request that DTX 62 be moved into evidence.

MR. JACKSON: Your Honor, we object. The witness has twice said he has never seen this patent before. It can be used for impeachment or whatever he wants for impeachment, but there's no basis to get it in through this witness.

THE COURT: Well --

MR. JACKSON: And can I explain why, Your Honor?

THE COURT: Okay. Go ahead.

MR. JACKSON: So yesterday we filed a motion for 52(c) that they had failed to provide any support for their idea that the '793 was prior art. What this is, is an attempt to replace that, to get this other patent into evidence on that to replace what they have done their whole case and find an alternative to the '793 that is earlier in the family.

They're trying to -- this is a backdoor way to come up with a justification for what their prior art is.

THE COURT: Is this, Mr. Davies, on the list of exhibits that you have for this case?

MR. DAVIES: It is, Your Honor. It's DTX 62.

THE COURT: All right. Yeah, that's right.

Well, so I'm going to admit it because there was no doubt that it actually is what he says it is, and, you know, Dr. Nathan can be cross-examined about it. And if I made a mistake here, you can tell me about it later. Okay?

(Thereupon, Defendant's Exhibit DTX 62 was admitted.)

MR. JACKSON: Okay.

MR. DAVIES: Thank you, Your Honor.

May I proceed?

THE COURT: Yes.

MR. DAVIES: Thank you.

BY MR. DAVIES:

Q. You testified yesterday as a part of your obviousness arguments that a POSA would not have a reasonable expectation of success with respect to Claim 14 of the '327 patent because a POSA would not be able to formulate a dry powder treprostinil based on the '793 patent; correct?
A. That's correct.
Q. And that's the understanding that you applied in your obviousness opinions with respect to Claim 14; correct?
A. That's correct.
Q. You agree that a dry powder inhaler was never tested in the INCREASE trial; right?
A. That's correct.
Q. And you understand that Tyvaso DPI was actually approved for treatment of PH-ILD based on results from the INCREASE trial using nebulized Tyvaso; correct?
A. That's correct.
Q. UTC didn't run any additional efficacy trials using their dry powder inhaler to secure an indication for that dry powder inhaler in PH-ILD; right?
A. That's correct.
Q. You mentioned -- I'll just touch on this briefly.

You mentioned the ACTIVE study yesterday.

Do you recall that?
A. I do.
Q. And I think you called it the closest study to

treprostinil; is that right?
A. That's correct.
Q. Iloprost is, obviously, a different molecule than treprostinil; right?
A. That's correct.
Q. And it has different pharmacokinetics and other properties that are different than treprostinil; correct?
A. Correct.
Q. For example, it has a shorter half-life than treprostinil?
A. Correct.
Q. You need to dose it more often than treprostinil?
A. Yes.
Q. And the actual formulation of the commercial product is very different from Tyvaso; correct?
A. It is different.
MR. DAVIES: Can we go to Faria-Urbina, which is DTX 348.
BY MR. DAVIES:
Q. And yesterday you spent some time talking with your counsel about Faria-Urbina; right?
A. Correct.
Q. And I think it's your opinion that -- I think you said Faria-Urbina was, at best, hypothesis-generating; is that correct?

A. That's correct.
Q. But you agree that the dosing that's described in Faria-Urbina was the same as the Tyvaso dosing that was used at the time; right?
A. Correct.
Q. And you agree that that dosing is also within the scope of the '327 patent Claim 1; right?
A. Correct.
Q. But it's your opinion that Faria-Urbina does not include PH-ILD patients; is that right?
A. I think that there's evidence that many of these patients would be categorized as pulmonary arterial hypertension and not PH-ILD.
Q. Is it fair to say that you really can't tell one way or another whether they didn't have PH-ILD because you're doing a retrospective rediagnosis, which is the same thing you criticized Dr. Waxman for?
A. That would be correct, yeah.
Q. Okay. Yesterday, counsel took you to the methods sections and you said that to properly diagnose PH-ILD, you would need CT scans and you couldn't do that in a retrospective context; right?
A. I said that you need to scrutinize the CT scan. You can do that in a retrospective context provided you look at a CT scan, ideally in the context of a multidisciplinary

discussion with a pulmonologist and a thoracic radiologist as recommended by our governing bodies.

Q. And if you look at what's provided on the screen here, it indicates that for these patients, Dr. Waxman's group reviewed the charts to identify patients with lung disease based on both a pulmonary function test and a high-resolution computed tomography scan of the lungs; correct?

A. I see that, yes.

Q. And that's exactly the evidence that you said yesterday that a POSA or a physician in this field would need to accurately diagnose a PH-ILD patient; right?

A. No, that's not what I said.

Q. Okay.

A. They don't specifically say that they looked at the CT scans themselves. They don't say they looked at it in conjunction with a thoracic radiologist. And based on this, they could have easily gone back and read a report from any radiologist who might not necessarily have expertise in interstitial lung disease.

Q. They say they reviewed these patients though; correct?

A. They say to identify patients with lung disease based on PFTs and HRCT scans of lungs.

But once again, they don't say that they

reviewed the CT scans or the reports of the CT scans.

THE COURT: And while Mr. Davies is thinking here.

MR. DAVIES: Yep.

THE COURT: Those are the right sorts of medical tests to have. Your point is maybe the right people weren't reviewing them?

THE WITNESS: Correct. I've seen many reports of CTs from radiologists without expertise. And then I look at the CTs myself, and they're totally off base.

So -- and really to validate that they have ILD, you have to look at the CT yourself. I mentioned yesterday the entity of interstitial lung abnormality --

THE COURT: Right, I don't think you need to repeat that.

THE WITNESS: Okay.

MR. DAVIES: Can we highlight on the bottom column there the -- looking at the ILD, presence of fibrosis. Do you see that, Rob? Go back. Nope. There we go. Keep going.

BY MR. DAVIES:

Q. So it says: "An ILD or presence of fibrosis defined as reticular septal thickening associated with architectural distortion with traction" -- I'm going to say this one wrong -- "bronchiectasis or honeycombing on HRCT."

Do you see that?

A. I do.

Q. And doesn't that indicate that Dr. Waxman's group would have reviewed this data in diagnosing these patients?

A. No. Once again, they don't state that they reviewed the CTs themselves, they just say what's there. And it could have been a report.

Sometimes when you do a retrospective analysis, it's very difficult to extract the CTs and look at the CTs yourself. That's one of the issues with retrospective analyses.

Q. You understand that these are actually patients that were being followed by Dr. Waxman's group at Brigham; correct?

A. They had been followed at Brigham, is my understanding.

Q. So if anyone would have access to that information, it would be Dr. Waxman's group; correct?

A. You would think that they would, but sometimes, even at my own institution, all we have are reports of CTs without actually having CTs.

MR. DAVIES: Can we please go to DTX 505. And let's look at Table S1.

BY MR. DAVIES:

Q. And, Dr. Nathan, yesterday you testified about

Table S1 in Faria-Urbina, and I think you said that when looking at this table, a POSA would be skeptical whether these patients had PH that was caused at least in part due to their interstitial lung disease because "this hemodynamic profile looks more like a PAH-type phenotype."

Do you recall saying that?

A. I did say that, yes.

Q. And you pointed to two specific patients yesterday, Patient 2 and Patient 3. And I'd like to look first at their mPAP. It should be 54 and 58.

And you said with respect to those two values for those two patients, that in your opinion, those patients were more likely to have Group 1 PAH, given those values; right?

A. That's correct.

Q. And you also looked at the PVR values, where are at the very bottom row there. And you pointed to the values of 8.9 for Patient 2 and 15.2 for Patient 3.

Do you see that?

A. I do.

Q. And, again, I think what you said yesterday was, again, that meant that these patients were PAH and not PH-ILD because you've never seen a PH-ILD patient with a PVR of 15.2 that was alive.

A. I did state that, yes.

MR. DAVIES: Okay. Can we go to Table 7 of the '327 patent.

BY MR. DAVIES:

Q. Table 7, again, is the baseline patient data from the INCREASE trial; right?

A. Yes.

Q. And you can see that the patient population in the INCREASE trial actually included PH-ILD patients that had an mPAP of 74?

A. Correct.

Q. Correct. And that's higher than the values you pointed to in Faria-Urbina supplemental Table 1; correct?

A. Correct.

MR. DAVIES: And those -- if you look at the PVR values as well. Can we highlight the PVR. Great.

BY MR. DAVIES:

Q. And for the PVR value, it -- the INCREASE study included PH-ILD patients with PVRs up to 18.05; right?

A. Correct.

Q. And in your opinion, you've never seen a PH-ILD patient with a PVR of more than 15.2 that wasn't dead; right?

A. That's been my experience, yes.

Q. Okay. But these patients were nonetheless enrolled in the INCREASE study; correct?

A. Correct.

THE COURT: Just for my edification.

For example, the 3.06 to 18.05 there, that's the minimum and maximum of the group?

THE WITNESS: That's correct.

THE COURT: Thank you.

THE WITNESS: There's more to this, though. If I may expand?

MR. DAVIES: I -- your counsel can draw that out. Dr. Nathan has a chance to --

THE COURT: I'll tell you what. Why don't you expand and I'll charge this time to the plaintiff.

THE WITNESS: Very good. Okay.

There were a number of patients who enrolled in INCREASE with hemodynamics like that, and we had a number of deaths very early on in INCREASE, within the first week or two. There's a very good chance that these were the patients who died as soon as they got into the clinical trial.

Now, if you go back to the Faria paper and those two patients, their hemodynamics --

THE COURT: Well, let's go back.

MR. DAVIES: Go ahead. Rob, can you go back to Faria-Urbina.

THE WITNESS: What's important is not only their

baseline, but their follow-up. So let's look at Patient 3 who started out with a PVR of 15.2. And then at follow-up -- and I'm not sure what the time period is -- the PVR had come down to 3.3.

That does not happen in PH-ILD. When you're talking about PH-ILD, you're talking about fibrosis of the lungs, fibrosis around the vessels. No pulmonary vasodilator is going to reverse that to cause a decrease in the PVR from 13.2 to 3.3.

To me, that bespeaks very much so that this is clearly a PAH patient just by virtue of that response we see there. And this patient was alive for whatever length of time versus the patients in INCREASE who likely died early on.

THE COURT: Okay. You can stop there, Doctor.

The time goes to the plaintiff.

Go ahead, Mr. Davies.

MR. DAVIES: Understood, Your Honor.

BY MR. DAVIES:

Q. You understand, though, Dr. Nathan, that these patients in Faria-Urbina would have been on treatment; correct?

A. Yes, correct, they were on treatment.

And actually, another point that didn't come up is that some of them were on treatments in addition to

inhaled treprostinil. They came in on other therapies as well, so how much of the so-called response can be attributed to inhaled treprostinil versus other drugs they're already on is uncertain.

MR. DAVIES: Can we go back to the '327. We can take this down, Rob, and let's go to column 26 of the '327 patent.

BY MR. DAVIES:

Q. And, Dr. Nathan, it's your opinion that the claims of the '327 patent are based on the results of the INCREASE trial; right?

A. Correct.

Q. And if we go to Example 3 in the '327 patent, you agree that there's a description of the INCREASE trial that starts here in Example 3; right?

A. Yes.

Q. And we've already looked at Table 7, which is part of Example 3, and that includes the baseline patient characteristics for INCREASE; right?

A. Yes.

MR. DAVIES: And if we go to Table 5, which is column 32 of the '327 patent. And, again, still on Example 3.

BY MR. DAVIES:

Q. Table 5 provides the summary of primary and secondary

endpoints in the INCREASE trial; right?

A. Correct.

Q. And in the '327 patent, Example 3, including Table 5 that we're looking at now, that provides the six-minute walk distance results from the INCREASE trial; right?

A. Correct.

MR. DAVIES: Can we bring up DTX 375.

BY MR. DAVIES:

Q. And DTX 375 is a provisional patent application.

Do you see that, Doctor?

A. I see that, yeah.

Q. And it was issued -- well, filed in the United States Patent and Trademark Office.

Do you see that at the top?

A. I do.

Q. Titled "Treatment For Interstitial Lung Disease"?

A. Yes.

Q. And that's the same title as the '327 patent?

A. You'll have to go to the '327 patent, which I think is more specific for PH-ILD. This says treatment for interstitial lung disease.

MR. DAVIES: Can we actually bring up the title of the '327 patent.

BY MR. DAVIES:

Q. And what's the title of the '327 patent?

A. It does say the "Treatment For Interstitial Lung Disease."

Q. The same title; right?

A. Correct.

MR. DAVIES: Can we go back to DTX 375.

BY MR. DAVIES:

Q. And you see that this was filed on April 17, 2020?

A. Yes, I do.

MR. DAVIES: Rob, can we go to -- it's DTX -- page 49 of DTX 375.

BY MR. DAVIES:

Q. And this is application number 63011810; correct?

A. Correct.

Q. And it was received April 17, 2020?

A. Correct.

Q. And this is a copy of the '810 provisional application that you mentioned in your opening expert report on infringement for the '327 patent; correct?

A. I believe that's correct.

MR. DAVIES: Your Honor, we request that DTX 375 be admitted into evidence.

MR. JACKSON: Your Honor, I don't think it's proper. I believe it was cancelled as of the priority date. Give me a second.

Sorry. I don't think it's relevant, Your Honor.

They conceded the priority date, and so I don't think this is any longer --

THE COURT: What is the point here, Dr. Davies?

MR. DAVIES: It's the priority application for the patent, Your Honor.

THE COURT: Right. But the priority date is not in dispute, so what is the relevance?

MR. DAVIES: Your Honor, we believe that they bear the burden on priority. We don't believe that they have shown that so we think it is an issue.

THE COURT: I thought it was stipulated.

MR. SUKDUANG: Your Honor, I'm sorry, it was not stipulated. And the pretrial order makes clear, and this goes to Mr. Jackson's point, in the pretrial order, paragraph 15, plaintiff takes the position that if -- we believe the '793 patent is prior art.

Plaintiffs argue that if we present prior art that's after the filing date, they bear the burden of evidence on proving priority. They contend -- they have now contended, and this is paragraph 15 --

THE COURT: Wait, exhibit -- Mr. Sukduang, I remember at pretrial conference, I believe, the parties told me the priority date was not in dispute.

MR. SUKDUANG: I don't think we -- I could be wrong, Your Honor. It wasn't in dispute because they didn't

raise this issue. And now --

THE COURT: You can't say it is not -- so that's a different thing if you say -- if you're saying they are now raising an issue that is not properly raised, then the response is it's not properly raised, not our stipulations are off.

MR. SUKDUANG: I don't think we conceded on priority. We have the record, and if we did, then the record says what it does.

They also -- this is an issue that's not properly raised. The '793 patent is admitted prior art in the specification of the '327 patent. This issue, the priority application, goes to the issue of the evidence Dr. Nathan talks about in terms of Example 3.

THE COURT: So whatever it is that they filed the motion about last night, that's locked into place as of the close of their case.

MR. SUKDUANG: Yes, it's locked in their case.

THE COURT: So if they have a good point, then it's too late to do something about it now. If they don't have a good point, then you don't need it.

MR. SUKDUANG: They don't have a good point, but the issue is -- this issue, this priority application, also goes to the issue of the evidence that Dr. Nathan points to.

Dr. Nathan points to you need this Phase 3

clinical trial to know -- for obviousness, for all these issues. And then he --

THE COURT: So if you're offering it for some limited purpose relating to Dr. Nathan's testimony -- and what is that limited purpose? That he is using art that is subsequent to April 17th?

MR. SUKDUANG: No. Dr. Nathan is not using any art. He is the plaintiff's side. He's arguing --

THE COURT: He's talking about art.

MR. SUKDUANG: He's talking about the INCREASE study, which is Example 3 of the '327 patent.

That's not in the priority application. There's no data from the INCREASE study in the priority application, which is the basis that he says you cannot know anything about these results unless you have the results.

That goes to this issue. Mr. Davies will take him and show him where the examples end and where the examples start. And Example 3 and 4 and 5 aren't there.

THE COURT: This is the provisional application for the patent-in-suit; right?

MR. SUKDUANG: Yes, which he relied on and he said he considered and it's on the exhibit list --

THE COURT: No, no. I agree with all that. I'm trying to get -- the objection was it's irrelevant and so that's what I was trying to get at, is it is relevant to

what? What are you trying to prove by offering it?

MR. SUKDUANG: It's relevant to the issue of whether you actually need the data Dr. Nathan says you need to file a patent application.

THE COURT: Okay. All right. So why isn't that a relevant point? I mean, I know why it's relevant. But why it's offered to prove that -- having something to do with the need for data, why is that possibly -- why shouldn't I admit it for that purpose?

In other words, what I understood them to be saying is they're not arguing about the priority date. They're arguing about what was in the provisional applications, whether that was -- shows that you don't need data, which is maybe their obviousness argument.

MR. JACKSON: Well, I actually think that is arguing about the priority date because they're saying certain things are in the --

THE COURT: All right. So why don't we do this. I'm going to let them admit it for cross-examining Dr. Nathan about it.

As far as I'm concerned, I have a distinct memory that you've said -- you've both said, in other words, you're not disagreeing with this, that the priority date is not in dispute.

And we've tried this case for three days and

everyone agrees as to what the priority date is, so I don't think it's in dispute.

MR. JACKSON: Yes. And just so the Court is aware, I said it in the transcript on page 9, lines 7 and 8. I explicitly said the priority date is no longer in dispute. So he said that was what was discussed at the final pretrial.

MR. SUKDUANG: That was not discussed at the final pretrial. Mr. Jackson said that.

THE COURT: Well, he said that and you were sitting there. And if he was not saying what was correct, that was the time you say no. So I think it's resolved.

And I think the behavior -- and behavior is not the right word. I think the conduct in the trial to date on this shows that it's resolved.

So I'm going to admit it for whatever purposes Mr. Davies can make here, but it's not going to change the priority date.

(Thereupon, Defendant's Exhibit DTX 375 was admitted.)

MR. JACKSON: Thank you, Your Honor.

MR. DAVIES: May I proceed, Your Honor?

THE COURT: Yes.

MR. DAVIES: Can we go to DTX page 30, please, Rob.

BY MR. DAVIES:

Q. And on DTX page 30, Dr. Nathan, you can see Example 2?

A. I can see it.

Q. And that's the same Example 2 from the '327 patent?

A. I'm not sure if it is or not. I'd have to compare this to the final patent.

Q. Sure.

MR. DAVIES: Can we go to the next page for the application, Rob.

BY MR. DAVIES:

Q. And you can see that there's no additional examples in this application; correct?

A. Is this the next page following on that?

Q. Yeah. Let's go to the next page. And you can see -- let's go to page 32. And you can see it goes to claims after that.

Do you see that, Doctor?

A. Yes.

Q. So this provisional patent application does not contain Example 3 that we've been looking at that has the data from the INCREASE trial; correct?

A. I probably have to relook at the whole document to make sure about that, but if you tell me that, then I'll take your word for it.

THE COURT: And it's in evidence so it's subject to absolute determination later on. Maybe Dr. Nathan doesn't know it off the top of his head.

MR. DAVIES: Absolutely, Your Honor.

Can we please go to the 2017 INCREASE protocol, which is DTX 8. Go to page 10.

BY MR. DAVIES:

Q. And you were looking at the arms and interventions yesterday with counsel?

A. Yes, I was.

Q. And you were asked about the starting dose of inhaled treprostinil in the 2017 protocol; right?

A. Correct.

Q. And I think your opinion was there was no starting dose; is that correct?

A. I think the inference from the insert when it says approximately 6 micrograms per breath, without saying it, I would read into that just one breath four times a day although it doesn't explicitly just say that.

Q. It says the other name for the inhaled treprostinil is Tyvaso; right?

A. Correct.

Q. And the dosing for Tyvaso at the time -- the starting dose for Tyvaso at the time of the 2017 protocol was a starting dose of three breaths; correct?

A. This is a new protocol. It's not necessarily following the label of the 2009 label. So it doesn't say.
Q. That's fine, Doctor, but you agree with me that Tyvaso was commercially approved and available at that time with a starting dose of three breaths; correct?
A. You'd have to go to the label to show me.
Q. You don't remember what the starting dose is for Tyvaso?
A. I'd want to see it to be sure that I'm answering correctly.

MR. DAVIES: Okay. Let's go to the 2009 Tyvaso label, DTX 357, page 3. And blow up the dosing.

BY MR. DAVIES:
Q. Do you see the initial dosage section, Doctor?
A. Yes.
Q. And can you read that, the first phrase of that?
A. "Therapy should begin with three breaths of Tyvaso."

It says "should." It doesn't say it has to begin. So it does allow physicians leeway. So it really doesn't change my interpretation on the 2017 protocol.
Q. And that was the approved dose of Tyvaso at the time of the 2017 protocol; correct?
A. Correct.
Q. Okay. Can we -- I want to talk a little bit more about your opinions that you offered regarding whether a

POSA would rely on Faria-Urbina. Okay?

And I think you said a POSA wouldn't rely on Faria-Urbina; correct?

A. Correct.

Q. And actually, it's your opinion that the analysis and data in Faria-Urbina is garbage; right?

A. I did use that word in my deposition; correct.

Q. Okay. And in your opinion, no rational POSA would rely on Faria-Urbina 2018; correct?

A. I'm not sure if I used the words "rational POSA," but I don't think a POSA would rely on Faria-Urbina.

Q. You testified yesterday, though, that Faria-Urbina was a reference that was relied on in the INCREASE study; right?

A. I wouldn't say relied on. It offered a glimmer of hope for patients, but it wasn't relied on.

Q. It was cited to in your *New England Journal of Medicine* publication along with Agarwal; correct?

A. It was, yes.

MR. DAVIES: Can we please bring up DTX 10.

BY MR. DAVIES:

Q. And this should be Saggar 2014, and this was the Saggar 2014 that you also discussed with counsel yesterday; correct?

A. Correct.

Q. Let's go to page 2. And in Saggar -- you can see Saggar also used CT scans for diagnosing these patients with PH-ILD; correct?
A. Correct.
Q. You were the associate editor of the *Thorax* journal at the time this paper was published; correct?
A. That's correct.
Q. And, in fact, you actually, I think you said, facilitated its publication; correct?
A. That's correct.
Q. And *Thorax* is a highly reviewed, highly regarded, peer-reviewed journal; correct?
A. Correct.
Q. So in your opinion, Saggar is not garbage; correct?
A. It's not garbage.
Q. It's your opinion that a POSA would not rely in any way on Saggar 2014 in the context of treating PH-ILD with inhaled treprostinil; correct?
A. Not at all. Different mode of delivery, different dose, entirely possible that a different result could emanate. And it was a highly select population with severe pulmonary hypertension. It didn't represent the spectrum of PH-ILD.
Q. If you have two drugs, in your opinion, that have a different route of administration and different amount of

the drug that's delivered that you described, you wouldn't know how the drug performed; correct?

A. Correct.

Q. I want to talk a little bit about your opinions related to a reasonable expectation of success.

And let's bring up Claim 1 of the '327 patent.

And, Doctor, in your opinion, only a randomized, controlled clinical trial would provide a sufficient proof for a POSA to have a reasonable expectation of success with respect to Claim 1 and the other asserted claims of the '327 patent; correct?

A. A randomized, controlled study as was done would prove the notion of improving exercise capacity.

Q. That wasn't quite my question, Doctor. I asked you, in your opinion and the opinions you offered in this case with respect to obviousness and reasonable expectation of success, only a randomized, controlled clinical trial would provide sufficient proof for a POSA to have a reasonable expectation of success with respect to the claims of the '327 patent; correct?

A. Yes.

Q. And anything less than a randomized, controlled clinical trial could not establish a reasonable expectation of success, in your opinion; right?

A. If we're talking generally versus with regard to

specifically to inhaled treprostinil, it would probably be a different answer. If you have, you know, multiple retrospective analyses --

Q. Doctor, my question was more specific than that. I'm just asking with respect to your obviousness opinions in this claim and specifically with respect to a reasonable expectation of success that you've offered opinions on in this case for the claims, in your opinion, anything less than a randomized, controlled clinical trial could not have provided a POSA with a reasonable expectation of success with respect to the claims of the '327 patent; correct?

A. In this case, the answer is correct.

Q. And, in fact, in your opinion, nothing short of the actual INCREASE trial results could provide a POSA with a reasonable expectation of success with respect to the claims; right?

A. Correct.

Q. That was the understanding you applied for your analysis in this case; right?

A. Correct.

Q. I'd like now to discuss a little bit your opinions on inherency. I'm sorry. Can we bring Claim 1 back up.

It's your opinion that Claim 1 requires virtually all of these PH-ILD patients experience an improvement in exercise capacity; correct?

A. No. I never said "virtually all."
Q. Okay. What is the standard that you're applying for inherency?
A. Well, for inherency, just that I understand correctly, it's the prior art inferring that the claim is true. Yes, you do need patients to unequivocally have this response in terms of exercise capacity. Inevitably and invariably, they should have this response.
MR. DAVIES: Can we bring up PDX 7.3.
BY MR. DAVIES:
Q. And you talked yesterday about the fact that the asserted claims are not inherently anticipated; correct?
A. I did.
Q. And it's your opinion today you did not require that virtually all the PH-ILD patients experience improvement in exercise capacity to render Claim 1 inherent; correct?
A. Could you repeat that, please.
Q. I don't know if I can.
THE COURT: Ask another question.
BY MR. DAVIES:
Q. With respect to Claim 1, is it your opinion that Claim 1 requires all -- virtually all PH-ILD patients to experience improvement in exercise capacity to be inherently anticipated?
A. Yes.

Q. Okay. And you applied that same requirement for inherent anticipation for all the other asserted claims in this case; right?
A. Correct.
Q. Dr. Nathan, yesterday Dr. Wertheim provided some opinions related to percent predicted FVC and absolute FVC. Were you here for those?
A. I was.
Q. And in your opinion, absolute FVC is more valid because you're measuring the patients against themselves at baseline and not the percent predicted; correct?
A. I think the two are complementary and it depends in what context you're looking at each of these.
MR. DAVIES: Can we bring up page 59 of Dr. Nathan's -- it would be the 2025 deposition. It's going to be starting at -- let's just bring up 59.
BY MR. DAVIES:
Q. So I was asking you some questions here about the use of FVC measurements in the TETON trial; correct?
A. Yes.
Q. And the TETON trial is a trial that UTC is conducting to attempt to verify the results of the FVC data that they saw in the INCREASE trial; correct?
A. Correct.
Q. Because, in your opinion, the FVC data from the

INCREASE trial, without further validation, is just hypothesis-generating; correct?

A. It's hypothesis-generating with regards to broader group and that's what we're looking at in the TETON study. We're not looking at PH-ILD. We're looking at patients with IPF and it's agnostic as to whether or not they have pulmonary hypertension or not.

Q. And if we look at your deposition transcript from earlier in this case, you can see you were asked: "Why did you choose absolute FVC as the measure of primary efficacy in the TETON trial as opposed to percent predicted FVC?"

And in your answer, you identified absolute FVC is for the standard for many of the IPF clinical trials.

And then you were asked: "Do you know why that's been the standard, absolute versus percent predicted?"

And you said a couple of things about percent predicted and then you respond: "Absolute is more valid, in my viewpoint, because you're measuring the patient against themselves at baseline and not the percent predicted."

Is that the answer you gave?

A. I did.

MR. DAVIES: I have no further questions at this time, Your Honor.

THE COURT: Thank you.

Redirect, Mr. Jackson.

MR. JACKSON: Just a few quick things.

REDIRECT EXAMINATION

BY MR. JACKSON:

Q. Now, just now on cross, Mr. Davies put before you DTX 62, was it?

MR. JACKSON: Mr. Smith, can you put that up, please.

BY MR. JACKSON:

Q. And this is the '507 patent that he put in front of you; correct?

A. Correct.

Q. Have you ever seen this patent before today?

A. I have not.

Q. Did Mr. Davies, after he put it up and moved it into evidence, ask you any questions about this patent?

A. He didn't ask specific questions about the patent.

Q. He just moved it into evidence and moved on; correct?

A. Correct.

Q. A minute ago, you were just asked about the reasonable expectation of success. And Mr. Davies asked you something about a reasonable expectation -- only a randomized, clinical trial would give a reasonable expectation of success and anything else would not establish that reasonable expectation.

Do you recall that exchange?

A. I do.

Q. Why do you have that view?

A. Because in this situation, there was such overwhelming evidence that using PH therapies for PH-ILD did not work. There was a lot of evidence of harm in patients who had previously been treated in randomized, controlled studied with PAH medication that, in this case, you needed a very well-done, large, randomized, controlled study to show and prove efficacy. It had a mountain of evidence it had to overcome in order to prove that Tyvaso works for PH-ILD.

Q. Is that based on those six studies we keep looking at in this case?

A. That's correct.

Q. And Mr. Davies asked you a lot of questions about the '327 patent and dry powder.

Do you recall these questions?

A. I do.

MR. JACKSON: Can you go -- Mr. Smith, can you pull up the '327 patent.

BY MR. JACKSON:

Q. You were asked about the need to get -- or about aspects of the dry powder.

Do you remember that?

A. I do.

Q. And when you were asked -- actually, strike that.

When United Therapeutics was -- sought FDA approval to get approval of its dry powder product, did the FDA require United Therapeutics to submit any dry powder information?

A. Yes, they did.

Q. What did they require United Therapeutics to submit?

A. There were PK studies, pharmacokinetic studies, showing equivalence or that it resulted in the same blood levels.

And then there was a conversion study. I get confused between the acronyms. I think it was the BREEZE study that showed patients could be converted from the nebulized form to the DPI version safely and effectively.

Q. So that's additional information the FDA required so that United Therapeutics could move from the nebulized version to the dry powder version; is that right?

A. That's correct.

Q. Was any of that information available to a POSA as of April 2020?

A. No. The approval for the DPI came after that. And so I believe the data supporting that was after April 2020.

Q. And so the safety and PK data for the dry powder all came after April 2020; is that correct?

A. I believe so.

Q. And did any of the data exist otherwise in the literature prior to April 2020?

A. No, not to my knowledge.

MR. JACKSON: Can you actually go to Tables 4 and 5. I think it's on page 40 -- Example 4 and 5 on pages 46 and 47.

BY MR. JACKSON:

Q. Are Examples 4 and 5 those studies?

A. It's a little blurry.

Q. Do you see Example 4 on page 46?

A. Yes.

Q. Is that the study you were just referencing?

A. Yes.

Q. And if you look at Example 5, is that also another study you were just referencing that was not available as of April 2020?

A. Yes.

Q. To a POSA, that is?

A. Correct.

MR. JACKSON: Nothing further. Your Honor.

THE COURT: All right. Thank you, Dr. Nathan. I think you're finally done, so you can step down. Watch your step.

THE WITNESS: Thank you, Your Honor.

MR. JACKSON: And with that, Your Honor, we rest

our responsive case to their validity case.

THE COURT: Okay. Thank you.

MR. SUKDUANG: And, Your Honor, given the time, we're not going to call Dr. Ogenstad. So I believe we have now closed our rebuttal to their rebuttal.

THE COURT: Okay. All right. So we're finished with the evidence portion of this case.

You know, in terms of the exhibits, I think you all are going to owe the deputy clerk some kind of identification of the exhibits that appear twice. But that doesn't have to be done now.

Is there anything we should do before reconvening at 11:30 for your arguments?

MR. SUKDUANG: Nothing from Liquidia.

MR. JACKSON: I think that addresses it for United Therapeutics. Thank you, Your Honor.

MR. SUKDUANG: It will be 11:30, Your Honor?

THE COURT: 11:30. And when arguments are over, I hope you will be ready to discuss the post-trial submissions timing, like -- things like that.

MR. JACKSON: Yes, Your Honor. And to the degree it matters, we would actually like our 52(c) motion resolved on the regular -- not on the basis of the -- all of the post-trial briefing can be resolved quicker.

And the reason we ask that is because we are

right here and there is a bar for them being on the market for this. It's a statutory bar, and they are currently on the market. So we would like that -- obviously, to have that addressed sooner rather than later.

MR. SUKDUANG: And, Your Honor, I think you addressed this yesterday. I had asked you that same question yesterday and you said do it in the post-trial briefs.

THE COURT: All right. Well, it's not going to be done today. So you can bring that up again after we've had the arguments. Okay. So --

MR. SUKDUANG: And in terms of the briefing schedule, I believe we sent a proposal to UTC.

THE COURT: Okay. No need to tell me about it. Just try to get to someplace where -- see what you can come up with between yourselves. Okay?

MR. SUKDUANG: Okay.

THE COURT: We'll be in recess until 11:30.

(A recess was taken, after which the following proceedings were had:)

THE COURT: All right. Please be seated.

It occurs to me that one thing that I should have done when I was talking to you before was suggest that the way we do this is plaintiff goes first and speaks about infringement. So probably not for very long but -- or

however long they want, and then they reserve the rest of it to respond to the defendant going first on invalidity.

MR. SUKDUANG: So I respond to him on infringement and then do the rest, and then he responds to me?

THE COURT: Yeah, yeah, you do it all as a package, but his invalidity -- or the plaintiff's invalidity response is after you've made your arguments on invalidity.

MR. SUKDUANG: That's fine with me, Your Honor.

THE COURT: Okay. All right. So, Mr. Carsten, I guess.

MR. CARSTEN: Yes, Your Honor. I have a few slides. May I approach, Judge?

THE COURT: Sure.

MR. CARSTEN: Thank you. And I promise not to read slides at you. I've taken your admonition to heart.

THE COURT: Okay.

MR. CARSTEN: So just to jump right in on that PDX 8.3, Your Honor, Liquidia elected to choose that 505(b)(2) pathway in which it relied exclusively on UTC Tyvaso's clinical efficacy data for approval.

And to be clear, the label itself -- now mind you, we're only talking about Claims 5, 6, 9, and 17. 1 and 14 are stipulated.

THE COURT: Yes.

MR. CARSTEN: The label itself includes data pertaining to the six-minute walk distance. So the label itself, in our view, establishes infringement for that claim.

And furthermore, because the label itself cites to INCREASE and the method used or described in that label would give rise to, more likely than not, the benefits of the therapeutic effects specified in Claims 5, 6, and 9, we believe those are met as well.

I'm reminded of the -- it's sort of dejá vu all over again. Three years ago we were here in front of the '793 patent -- in front of you for the '793 patent. And you had held that the '793 patent was pertaining to hemodynamic effects.

And the same argument was made: There's no hemodynamic effects specified in the label. There's no requirement to measure. And Your Honor said, you know, it just needs to instruct doctors and patients to administer a single-event dose that is therapeutically effective. The LIQ 861 label does so by instructing doctors and patients to administer it.

That's exactly what we have here.

But even if there were not enough, we have a launch, and so we're able to look outside the label, assuming you're limited to--

THE COURT: But we don't have any evidence about the launch on the record; right?

MR. CARSTEN: Well, I did ask Dr. Channick about that and he confirmed that the product was on the market.

But regardless, the label -- the FDA -- Liquidia petitioned the FDA for the supplemental NDA on this matter and said, we want to rely upon not just the package insert for Tyvaso, but also treprostinil peer-reviewed literature. And the FDA agreed and allowed it over that.

And so when you include the Yutrepia label with the INCREASE publication, there is no doubt that, more likely than not, a patient receiving this -- the drug under the claimed method would experience those therapeutic effects of 5, 6, and 9.

THE COURT: So in 6 and 9 where the therapeutic effect was described as a statistically significant reduction, what does -- how is that measured? Or how is that determined? Whether or not something that's going to occur in the future and following the method that's described in Claim 1, how are we going to know what number is a statistically significant reduction?

MR. CARSTEN: Well, Your Honor, I think that's exactly the crux of medicine here; right? So you have the clinical trial which establishes efficacy for -- in this population by a statistically significant measure.

Once you have that, then you know that it's more likely than not that a patient being administered this method and receiving the drug, if they see a benefit, it will be a statistically significant one.

Now, there's additional claims --

THE COURT: So wait. So statistically significant is -- because you can't tell whether something is statistically significant when it happens to one person.

Is this -- is the claim, essentially, incorporating by the reference to a statistically significant reduction the numbers that are described as statistically significant in the INCREASE trial publication?

MR. CARSTEN: No, Your Honor. We don't see it that way. And I think Dr. Thisted did try to explain this, that it's not as if there's a statistical significance hurdle that -- for example, and I think we saw 1.07 percent for FVC percent predicted increase and a p-value that said that's statistically significant.

THE COURT: Right.

MR. CARSTEN: But that was the average over the entire -- or the statistical measure over the whole population.

So it's not as if, if a patient sees a 1.07 percent benefit, if they're over that, it's statistically significant, and if they're under that, it's not.

What these claims require --

THE COURT: So if that's not the measure, what is the measure in a particular patient? If they do .59, does that meet the claim?

MR. CARSTEN: Yes, Your Honor, we believe it would.

THE COURT: If they do minus .16, does that meet the claim?

MR. CARSTEN: Well, minus .16, I think there's a situation where the patient would not be receiving the therapeutic effect benefit. And so that --

THE COURT: Any increase at all no matter how small, that meets the claim?

MR. CARSTEN: I believe that is correct, Your Honor. Because that patient would be a member of the population as if -- and so we know that on a population basis, that that patient would be included in the therapeutic benefit category, and that number populated that statistically significant determination.

And so Your Honor could think about this as a hurdle, but remember, these claims don't require a measurement. They don't require that there's any actual measurement. Just like the hemodynamic benefit in the '793 wasn't required to be an actual measurement.

THE COURT: But it's hard to say it doesn't

require a measurement when it's talking about improvements in things that can be measured.

MR. CARSTEN: I understand, Your Honor. But I think we had this discussion with Dr. Channick when he was on the stand. And that is, do you disagree, sir, that a patient receiving this treatment under this method would more likely than not experience that benefit. And even if it's not measured.

We're talking about in the context --

THE COURT: You're saying -- when you say more likely than not experience this benefit, the benefit in your position is the benefit is any non-zero benefit in anything that was measured in the INCREASE trial?

MR. CARSTEN: Yeah, if -- well, not exactly. I think for Claim 5, for example, you have to be looking at --

THE COURT: Well, Claim 5 -- I'm not talking about Claim 5. That gives an actual measurement. And yes, it seems to me, there's a very reasonable basis to believe that people who are treated with this, a substantial number of them will meet that.

MR. CARSTEN: Right.

THE COURT: But I'm asking about Claim 6 and 9.

MR. CARSTEN: Oh, I see.

With respect to exacerbations, in the statistical population, it's tough to say there is a

reduction of exacerbations. As Your Honor will remember, that's a serious event that usually, typically leads to somebody going to the hospital; right?

And it's tough to say, well, because you took this drug, you didn't have one of those events. But on the population basis, that was one of the surprising results from INCREASE, was that we're able to determine that people who take the drug are, more likely than not, going to experience that benefit.

THE COURT: So even an individual who suffers a bunch of exacerbations, logically, there's no reason why they aren't included in the claim even though they're getting less-than-zero benefit probably?

MR. CARSTEN: The statistical analysis shows that if that patient were -- had been in the INCREASE protocol and the INCREASE trial, it was more likely than not that they would have seen that benefit.

And so that's the proof that establishes and allows confidence for the treating physician to say, I'm going to give you this drug product according to the label, and I expect that it's going to provide you with reduced excursions -- or exacerbations, excuse me.

THE COURT: Well, the claims are that it provided, not that it's expected. The claims are they will happen.

MR. CARSTEN: Right. And it's -- and the infringement standard is more likely than not.

And I submit that the label in combination with the INCREASE data establishes it's more likely than not for a patient having received the drug product that they will receive -- they will experience a reduced number of exacerbations.

THE COURT: So earlier when I asked you -- we were talking about not exacerbations but maybe something more like the forced vital capacity. Even though the claim talks about providing a statistically significant improvement, a patient who gets a non-zero improvement is someone who is having the method practiced on them, in your opinion?

MR. CARSTEN: Yes, Your Honor.

THE COURT: Okay. I'm sorry. I don't want to use up all your time with my questions.

MR. CARSTEN: Thank you, Your Honor. If you have -- we're here at your pleasure. So if Your Honor has questions, I'd rather spend the time addressing that.

THE COURT: That's the main question I have about infringement at this time.

MR. CARSTEN: Thank you, Your Honor.

THE COURT: All right. Mr. Sukduang.

MR. SUKDUANG: Just so I can try to keep track

of time, Your Honor.

THE COURT: As long as you're not recording us.

MR. SUKDUANG: I'm not recording. I don't want to hear myself. I'm thankful that you're willing to listen to me. I have documents, slides I'd like to hand up. May I approach, Your Honor?

THE COURT: Yes.

MR. SUKDUANG: May I begin, Your Honor?

THE COURT: Yes.

MR. SUKDUANG: Sanya Sukduang for Liquidia.

Your Honor, as I started in my opening, UTC was able to get a label expansion for PH-ILD which is now on the Tyvaso label in 2021. They did that using the exact same drug, Tyvaso; the exact same route of administration, inhalation; the exact same formulation, solution; and using the exact same dosing. In fact, the 2009 dosing is the same as '21 dosing.

How did they do that? They did it through the INCREASE study, as you heard. And not only did they get a label expansion, they have a patent expansion, the '327 patent, and that '327 patent goes 20 more years longer than any other patent they have listed in the *Orange Book* for Tyvaso or Tyvaso DPI.

How did they get there?

THE COURT: Let me interrupt you for a second.

You could be -- you, Liquidia, also decided to get a label expansion, so to speak. You could be on the market with no questions if you had just gone with the initial indication; right?

MR. SUKDUANG: With respect to this particular patent, the '327 patent?

THE COURT: Yeah.

MR. SUKDUANG: Yes. But then we had the '793, which we litigated.

THE COURT: But that's gone.

MR. SUKDUANG: And there's a new lawsuit -- without the '327 patent, yes. That pertains to PH-ILD only.

THE COURT: So to some extent, while you're talking about them getting a label expansion, your being blocked on the market for another 20 years is at least partly because of your decision to try to get the whole market and not just the part of the market that to date you have won.

MR. SUKDUANG: It's not based on us trying the get the whole market. It's based on them getting another patent and never this product. And how did they do that? That's the point, Your Honor.

What UTC is trying to do is stop doctors from doing exactly what they were doing since 2009, unless they buy their drug. And UTC, the record is clear since 2009,

doctors like Dr. Saggar, Waxman, Tapson, Channick, and Hill use Tyvaso to treat PH-ILD patients. And I know you're going to have to assess whether the record says that, but that's what the testimony was. That's what the documents show. They used Tyvaso to treat PH-ILD patients. They used --

THE COURT: For what it's worth, I don't actually have a lot of hesitation in saying that I credit their testimony that that's what they were doing.

MR. SUKDUANG: Your Honor, I appreciate that. How it all happened is they did this: They reported those outcomes to UTC. Dr. Waxman, Tapson, and Dr. Saggar wrote those outcomes down for Faria-Urbina and Parikh in peer-reviewed journals, and Saggar, peer-reviewed journals. They told everybody they did this.

And Dr. Waxman went to UTC and you heard this from UTC witnesses themselves. Dr. Smith, Mr. Laliberte, the conception or the idea of INCREASE itself was based from Dr. Waxman's presentation in 2015 and the Agarwal data. That's how they started INCREASE and that's where INCREASE went from there. And Dr. Waxman gave them the dosing and the patient population.

And what they want to do -- they're fine. They did the INCREASE study. That's not the problem. The problem is they're taking someone else's work in the prior

art and now trying to get a claim on that and stop everybody from doing what they were already doing unless they buy Tyvaso. And we get to the infringement, Your Honor.

And if we could bring up the claims, please.

I'm going to focus on 5, 6, 9, and 17. You heard from Liquidia's Mr. Adair, who testified by video, that Liquidia cannot promote, instruct, encourage a doctor to do anything that's not approved on the FDA label. Dr. Nathan, Dr. Channick, Dr. Hill agreed with that. Liquidia can't do that. UTC can't do that.

THE COURT: But you can actually do that as of today; right?

MR. SUKDUANG: I can tell you for a fact when you look at the Yutrepia label, we are not doing that. We are not encouraging, instructing, anything with respect to NT-proBNP FVC --

THE COURT: But you are instructing how to, let's say, perform the method. Leave aside the results.

MR. SUKDUANG: Of Claim 1. We admitted infringement of Claim 1. So we are -- on our label, we give a dose, and we say "exercise capacity." So you're right and we acknowledge that. So there's no dispute with that with respect to Claim 1.

The issue is the other claims. We still have to instruct, encourage, induce those other things. And

Dr. Nathan agreed with Mr. Adair that Liquidia cannot do that. Dr. Nathan agreed that the Yutrepia label is not indicated for NT-proBNP in any manner, for FVC in any manner, for exacerbations of ILD in any manner. It's not approved for six-minute walk distance or 10 meters. That is not the indication.

And you do not have to run a six-minute walk distance to assess exercise capacity. Dr. Nathan agreed. Dr. Channick agreed. Dr. Hill agreed. Dr. Waxman provided testimony that he prefers the three-minute walk test, step test. And that you can also -- the most convincing evidence is a patient coming in and saying, "Hey, I can walk to my mailbox and before I couldn't get off the couch."

All of those are valid measurements of exercise capacity that doctors use in real-world clinical practice. Six-minute walk test might be done in clinical trial. We're not talking about the clinical trial here.

Dr. Nathan agreed NT-proBNP, FVC, exacerbations, those words are nowhere on the Yutrepia label and no data related to those are on the Yutrepia label. There's no instruction to treat more than one patient at a time. There's no instruction to conduct any statistical analysis, to aggregate data, nothing with that. There is nothing on the label, in our opinion, that would lead to direct infringement of the dependent claims.

You were going to ask a question, it looks like.

THE COURT: I thought you were going to say there to indirect infringement.

MR. SUKDUANG: I'm getting to direct first because doctors have to directly infringe. Doing Claim 1, every single one of these claims -- 5, 6, 9, 17, and Claim 1 -- require some type of measurement or outcome to be observed. They require it. The NT-proBNP has to happen.

THE COURT: It has to happen. They don't certainly have to measure.

MR. SUKDUANG: Then how do you know?

THE COURT: That's a different question. But it doesn't say you have to measure it.

MR. SUKDUANG: As you pointed out, 200 picograms is the specific value the claim requires. Dr. Channick testified that you cannot know 200 picograms was met unless you measure NT-proBNP before you administer and then measure at some point after 8, 12, 16 weeks. It just doesn't happen. And how do we know that? Because the INCREASE trial didn't have it happen all the time. So these claims require something to be done.

THE COURT: I don't think I'm going to agree with you on that.

MR. SUKDUANG: I'll move on to the next issue with respect the inducement. Again, with respect to

inducement, there has to be something on the label doing this. When you looked at Dr. Nathan's for Claims 5, 6, and 9, the only thing pointed to was *New England Journal of Medicine* article. That's the only thing he pointed to.

THE COURT: The one that reports the results of the study?

MR. SUKDUANG: Yes. The Waxman paper. Dr. Nathan testified that the only thing a doctor needs to read to safely and effectively treat patients with Yutrepia is the label itself. He testified that the *New England Journal of Medicine* article is not cited in the Yutrepia label. It's not incorporated by reference. It's not directed. There's nothing in the Yutrepia label that tells doctors to go read something outside the label with respect to any of those claims.

Dr. Hill, Dr. Channick --

THE COURT: So Mr. Carsten said -- and I have no independent memory at this time -- that you made a similar argument regarding hemodynamics in the '793 patent and that I, nevertheless, ruled against you. Assuming that's true, why is this any different?

MR. SUKDUANG: Because those claims are entirely different. Those claims don't have these outcomes required. Those claims, the '793 claims, say give the drug by inhaled in a therapeutic amount in a single-administration dose.

That's it. There was nothing in those claims that said, oh, this number has to be reached, a statistical significance needs to be reached.

THE COURT: You're saying in so many words what I decided three years ago about hemodynamics was, I guess, the therapeutic effect that the hemodynamics showed there was indicated?

MR. SUKDUANG: The hemodynamic effect showed just pulmonary hypertension. And remember, pulmonary hypertension is just, as we heard, those hemodynamics; right? These are completely different claims in terms of the outcome --

THE COURT: Okay. Well, so let's not argue.

MR. SUKDUANG: So on inducement --

THE COURT: So, you know, that's something that you can bring up in your briefing.

MR. SUKDUANG: Sure.

THE COURT: Or he can bring it up in the briefing and I'll sort that out later.

So go ahead.

MR. SUKDUANG: So on inducement, again, the label has to instruct. There's no instruction to do anything in 5, 6, 9, or 17. It's not indicated for. It's not in the label. Dr. Nathan agreed. Dr. Channick testified to that. Liquidia cannot do anything that is not

in the label.

What Dr. Nathan pointed to was the *New England Journal of Medicine*. I spoke about that. It's not in there. The second thing, the only other thing he pointed to, was a product dossier for Yutrepia. And he admitted and Dr. Channick agreed that the product dossier is not meant for doctors. It's meant for insurance companies.

So they're not instructions for doctors on how to use Yutrepia. And in the product dossier itself on page 2, Dr. Nathan and Dr. Channick agree that it says this is not marketing material and it is not instructions on how to use Yutrepia. You have to go to the label for that.

With respect to the Yutrepia label, Dr. Nathan didn't point to this, but Section 6.1 says: "With respect to Yutrepia, you cannot take clinical trials with a different drug and equate them to Yutrepia."

That is the instruction on the Yutrepia label itself. The FDA had to review that. If they disagreed with that, they would have made us remove it. When you look at the totality of the Yutrepia label, we believe there's no direct infringement.

But more importantly, to inducement of infringement, Your Honor, there is nothing inducing infringement of Claims 5, 6, 9, and 17. The simple fact that --

THE COURT: I understand your argument. And basically, what you're saying and will presumably cover in the briefing is, essentially, the legal point that what you seem to be saying is unless there's an express instruction that has all the elements of the claim, you can't be inducing infringement.

MR. SUKDUANG: I think whether you look at expressed or implicit, there's neither here. It's an absence. And in that instance, Your Honor --

THE COURT: So you could add something where it doesn't expressly indicate an element of the claim, but it could be implicit, and then that would be inducing?

MR. SUKDUANG: No. You can't have an implicit inducement.

THE COURT: Why did you just a moment ago say it doesn't have anything --

MR. SUKDUANG: No, I said the label doesn't. I apologize if I misconstrued your question.

THE COURT: Well, let's put it another way, just you were saying -- you said it doesn't have an express or implicit, you know, direction to do this, so I took it you were saying that the reason to say that is if an implicit was -- counted for inducement --

MR. SUKDUANG: Okay. I understand.

THE COURT: Do you understand what I'm saying?

MR. SUKDUANG: I do.

No. Implicit cannot count for inducement. There has to be specific intent, specific intent on Liquidia's part to provide instructions to induce infringement of that claim.

Implicit -- and this goes to the skinny label world. We're not a generic drug, but a generic drug -- every doctor knows for a generic drug, if there's two indications -- and a generic skinny label is about one -- every doctor already knows that that generic drug, because of Hatch-Waxman pathway, can be used for that other indication. That it would work; right?

But they can skinny-label it out. And that creates no inducement. Under your scenario, that would also be implicit because everybody just knows and you just say drug X and here's the dose.

In those situations, the Federal Circuit has held that is not induced infringement. You have to have explicit instructions to do so. Otherwise, the skinny-label world would -- could not exist. It would not exist.

And under UTC's scenario, that is exactly what they're arguing. They're saying, you don't have to have it on the label. Just look at the results of the clinical trial. If that's the case, then every generic drug that tries to skinny label would infringe a claim directed to an

indication that is not on the label.

It would infringe any claim directed to the outcome of that method on that patent even though it's not on the label. And we know that is not the law.

Moving to obviousness, Your Honor, if I may. Is that okay?

THE COURT: Yes.

MR. SUKDUANG: Moving to obviousness, Faria-Urbina, the '793 patent, and Saggar 2014 render all the claims obvious.

THE COURT: Okay. And so I don't want to dig a deeper -- a deep core here, but in terms of the status of the '793 patent as prior art, can you just give me the one-sentence preview of what your response to the motion --

MR. SUKDUANG: It might be one long sentence.

One, it's prior art under 102(a)(1).

Two, it's admitted prior art in the '793 patent. Under the law, they can't get that.

Three --

THE COURT: Wait. So I understand it's prior art under 102(a)(1). I understand that, those words. And is that -- why is that?

MR. SUKDUANG: Because the disclosure was available to the public before the effective filing date of the '327 patent. The disclosure that's in the '793 patent

was available to the public prior to the effective filing date of the '327 patent.

THE COURT: And you say the disclosure because it was in the priority chain or because --

MR. SUKDUANG: It's -- well, we believe, one, it's in the patent itself, but it's also in the priority chain.

THE COURT: But the patent itself, did that become public before it was issued?

MR. SUKDUANG: Did the -- the application was published -- yeah, it was published before it was issued. That's the way, the normal course of --

THE COURT: Well, it depends on how fast. I thought it was 18 months.

MR. SUKDUANG: It didn't go that fast. And with respect to the disclosure, it's out there. It's admitted prior art in the '327 patent.

THE COURT: What do you mean, it's admitted prior art?

MR. SUKDUANG: So under the law, if someone admits that the disclosure or the information is in the prior art, then it's a -- then they can't escape that admission.

THE COURT: And there's somewhere in the '327 patent, where these inventors say the '793 patent is prior

art?

MR. SUKDUANG: They say it's disclosed. And what the case law says, that you don't have to say it's prior art. You just say the subject matter is disclosed. That's what they did with the '793 itself.

With the '507, which is the same spec, with that WO/2019, they pointed to all that. In fact, UTC -- and the reason why priority -- I looked back at the transcript, Your Honor. With respect to priority not being contested, that was with respect to our 2020 invalidity, the February 2020 press release defense that we withdrew because you said we didn't bring it up on time.

THE COURT: I think we did all that before we had the pretrial conference.

MR. SUKDUANG: No, no, no. We withdrew it going into the pretrial conference because you issued a ruling on that. That forced us to do it before the pretrial conference.

THE COURT: Right. So that's not what --

MR. SUKDUANG: I mean, we would have kept it in had you not said we couldn't, so.

THE COURT: Right, right. But in other words, it was gone so -- I don't understand why the fact that you were raising priority with something that was now gone has any impact on what you said at the pretrial conference or

what the plaintiff said that you obviously should have objected to if it wasn't true.

MR. SUKDUANG: Well, because the way -- when you read the transcript, Your Honor asked is this priority issue moot, because they had a motion on the -- they had a motion which -- it's not a Daubert motion. It was the objections to report and recommendations of the magistrate judge. And that -- with that issue, the priority became moot.

And when you read the transcript, what was -- what was discussed about that issue, they didn't bring up '793 priority -- prior art. And we believe it is, but now they're saying it's not prior art.

And when they're saying it's not prior art, in the pretrial order itself, paragraph 15 says they have to present evidence if there's prior art that they contend is after April 20th. They have to present evidence establishing their --

THE COURT: Oh, so that's -- you know, I was wondering in the pretrial order -- so we'll come back to this, but why don't we just assume it's prior art and move on.

MR. SUKDUANG: Okay. I apologize, Your Honor.

THE COURT: No, no, no, no. I'm the one that brought it up. But I'm not apologizing so you don't need to apologize.

MR. SUKDUANG: I wish my life worked like that most of the time, but thank you, Your Honor.

So going back to what I was saying, Faria-Urbina, '793 patent, and Saggar render all the claims obvious. There's ample motivation to combine those three references. As Dr. Channick testified, all three are directed to treprostinil. All three are directed to PH-ILD. All three disclose the exact dosing in Claim 1 of the '793 patent. And they all disclose improving exercise capacity explicitly.

With respect to Faria-Urbina and the '793 patent, they're also directed to the same group of administration, inhaled. There's ample motivation to combine those because they teach the same patient population using the same drug and the same dosing to try to achieve the same outcome. That's motivation to combine.

A person with skill in the art would be motivated to combine Saggar even though Saggar is IV treprostinil. Why is that? Again, the exact same drug. They're treprostinil. They work in the same mechanism of action. They're looking at the same patient population.

And as Dr. Channick testified, a person of skill -- and remember, Saggar is before both of these. A person of skill in the art would look at Saggar and say, oh, these are good findings, but as other people recognized,

maybe there's an issue with systemic vasodilators.

Saggar didn't see it, but let's just avoid that issue altogether and go to inhaled. So you combine what you get from Saggar and IV, you'd go to the inhaled route because, as everybody testified, when you inhale it, it's localized administration. You avoid that potential systemic side effect. There's ample motivation to combine.

Dr. Nathan's testimony about the seven deadly studies further supports the motivation to combine Saggar with Faria-Urbina and '793. There's no dispute that those studies don't involve treprostinil and there's no dispute that six of them deal with oral administration of non-treprostinil drugs.

But Dr. Nathan testified yesterday that they all have the same mechanism of action, vasodilation. He testified yesterday that a person of ordinary skill in the art would expect them to have the same effect as treprostinil even though they're different drugs, even though they're different routes of administration.

If Dr. Nathan can say that with respect to those studies that he said failed, then when you look at Saggar, which is the exact same drug, the exact same mechanism of action, then clearly you'd be motivated to combine that even if it was IV because it provides valid results that are useful to a person of ordinary skill in the art looking to

improve on those studies.

The prior art and obviousness doesn't need to change every single thing. You just have to have a motivation to combine. We believe there is.

On expectation of success, Faria-Urbina and the '793 and Saggar disclose the results that are claimed. They disclose the results that are claimed. We believe the fact that they literally disclose the results is an expectation of success -- a reasonable expectation of success to get the claimed outcome.

But there's more than that.

THE COURT: When you say they disclosed the results, what's the best results that they disclosed?

MR. SUKDUANG: Sure. Two points on that. Faria-Urbina Tables S3 and S4 are directed to --

THE COURT: Those are the -- like, three patients and three patients; right?

MR. SUKDUANG: Correct. But the claim is only directed to one patient. Faria -- and we're talking about expectation of success, not anticipation. Although it anticipates.

Faria-Urbina Tables S3 and S4, PH-ILD in Table S3, PH-CPFE in Table S4, which are PH-ILD patients, expressly disclosed six-minute walk distance. Dr. Nathan said six-minute walk distance is exercise capacity. They

expressly disclose 21 and 55 meters respectively in increase in six-minute walk.

That's Claim 17. That is literally disclosing that. They have the same dosing. Dr. Nathan admitted Faria-Urbina is the dosing of Claim 1.

With respect to '793, UTC admitted to the PTAB and the FDA that the claims of the '793 are treating PH-ILD patients to improve their exercise capacity. That's Claim 1. '793 patent is the same dosing as Claim 1.

Those are the two pieces of evidence that clearly disclose Claim 1 and Claim 17.

Saggar, again, although IV, discloses improvements in six-minute walk. He disclosed Claim 5, more than 200 picograms per milliliter of NT-proBNP. He discloses the same magnitude of FVC.

THE COURT: So Saggar disclosed, I think it's BNP; right?

MR. SUKDUANG: BNP. And Dr. Channick testified and Dr. Saggar testified that BNP and NT-proBNP are just measurements of the same thing.

THE COURT: Was that the testimony or was the testimony more like NT-proBNP, whatever exactly it was, he described it as like a sliver or --

MR. SUKDUANG: I think it's a precursor. I can't remember, Your Honor, if BNP is the final or the

precursor. That could be one or the other.

THE COURT: The point is whatever his testimony about that, it's pretty hazy.

MR. SUKDUANG: Yeah. I believe if you go back to Dr. Saggar's testimony and, again, with Dr. Channick, they measure this outcome, the BNP, the NT-proBNP, because they tell you the same thing.

THE COURT: So you believe that somewhere in Dr. Saggar's hour-plus of testimony he said BNP and NT-proBNP measure the same thing?

MR. SUKDUANG: I think Dr. Saggar and Dr. Channick because you actually asked Dr. Channick some questions about what do you measure? Do you measure this? And he said, "Our group at UCLA measures the BNP." But it tells you the same thing, if I remember his testimony correctly, he said it relates to some sort of peptide produced when the heart isn't functioning a certain way. You measure that as a measurement that you look for for a PH or PH-ILD.

THE COURT: I guess what I'd say is in the briefing you submit, it would be worthwhile for you to persuade me that something that discloses BNP is good for disclosing based on what a person of ordinary skill in the art would understand.

MR. SUKDUANG: Absolutely, Your Honor. Thank

you for that direction.

Going back to expectation of success, if I can, Agarwal, Parikh, Dr. Channick talked about that. You heard from Tapson, you heard from Dr. Parikh, both authors of Parikh 2016. You heard from Dr. Waxman about Agarwal. Those all also provide a reasonable expectation of success in achieving the limitations of the asserted claims because, again, it's inhaled treprostinil. It's Tyvaso. Both of them literally disclose the exact same dosing as Claim 1 in the INCREASE study. They disclose improvements in various outcomes including exercise capacity and six-minute walk. Those are expectation of success documents that a person of skill in the art would look at in the totality of the evidence.

Dr. Rothblatt's 2018 earnings call also relies -- she specifically said, "I talked to Dr. Waxman. This drug works." That's expectation of success. Dr. Rothblatt acknowledged that looking at posters and presentations, and she used that word "UTC powered the study" and she specifically said INCREASE and PERFECT. The only posters and presentations related to Tyvaso and PH-ILD are Agarwal, Parikh, Faria-Urbina. Those are the posters Agarwal and publications, Parikh and Faria-Urbina, because Dr. Nathan said everything else is other drugs. That provides a reasonable expectation of success to a POSA. And

that was well before the priority date.

You heard from Dr. Smith. He testified that the reason why UTC did the INCREASE study is because Dr. Waxman came in. He submitted his Agarwal abstract before it was published, talked about it. Dr. Waxman testified after that presentation the then-president of UTC said, "We're going to do this study."

That's not only his testimony. It's reported in documents from UTC. There's a proof-of-concept document that Dr. Smith talked about and others. There's an investigator brochure. There's presentations that Dr. Smith generated internal consumption and external consumption prior to 2020 that said -- pointing specifically to Agarwal, that it is supportive evidence of Tyvaso in ILD.

THE COURT: One of the principles that I remember is the route that the plaintiff took to inventing the invention can't be used to show obviousness.

MR. SUKDUANG: And that's a very good point. Dr. Smith didn't join INCREASE until after the protocols were finished. He testified to that.

THE COURT: Yes.

MR. SUKDUANG: Dr. Peterson testified to that. And the invention, they say, was the result. Dr. Waxman came in 2015 before there was a protocol even in place and brought this information.

And those presentations, Dr. Smith wasn't there. He wasn't involved in this project at that time. And Dr. Waxman's PowerPoint presentation back in 2015, which was discussed with nobody who was an inventor at that time, made UTC do this.

THE COURT: I think I understand what you're saying, which is you agree with the principle I just said. But you're kind of relying on Dr. Waxman and he's not part of the invention process.

MR. SUKDUANG: None of the people who were at that meeting were part of the invention process. None of those people. UTC, a company, is not an inventor.

THE COURT: I understand that.

MR. SUKDUANG: Only individuals. And none of the individuals, Dr. Deng, Peterson, Smith, had anything to do with that 2015 meeting.

THE COURT: Okay. So all right. Yes, I understand that.

MR. SUKDUANG: Going to Claims 1 and 17, we talked about it briefly. What's the best evidence? It's Faria-Urbina and '793 patent. I went through those with respect to Tables S3 and S4 and UTC's acknowledgment. We believe that the combination of Faria-Urbina and '793 renders obvious.

I know I'm going over my time, Your Honor. I

apologize.

THE COURT: That's all right. I think I said yesterday it's at my discretion.

MR. SUKDUANG: With respect to Claim 14, again, the '793 patent literally discloses a dry powder inhaler and a dry powder formulation of treprostinil inhaled. You would be motivated to combine that with Faria-Urbina that renders Claim 14 obvious.

Counsel wants to point to your prior decision in 2022. This issue actually came up and you made judicial findings. We argued that dry powder was not enabled and not described in the '793 patent. They argued the opposite, that as of 2006, a person of ordinary skill in the art could more than easily enable a dry powder inhaler of treprostinil and a dry powder formulation. We lost on that.

And now they had Dr. Nathan come up and say in 2020, two decades later or slightly less than two decades later, no one would know how to do this. It's just not credible, Your Honor, based on the '793 patent, based on the disclosure of the '327 patent.

THE COURT: I thought of other reasons. I thought -- I had my doubts about what Dr. Nathan was saying about that and I believe that he was saying a medical doctor wouldn't know how to do that. But I don't remember the exact POSA definition, but clearly, other kinds of people

knew how to do that.

MR. SUKDUANG: Sure. And he acknowledged that. But then how is the claim valid if people knew how to do it, if UTC admitted that you can do this as of 2006? And that's enablement. That's things outside of the spec of the '793. How can UTC legitimately say in 2020 that a dry powder formulation of treprostinil and dry powder inhalers, no one knew how to do it.

In fact, we addressed this very issue in claim construction. You remember the dry powder issue?

THE COURT: So just -- I don't remember claim construction. But I guess what I'd say is you're citing to a lot of things that are actually not part of the record of this trial.

MR. SUKDUANG: No. The '327 patent is part of the trial. That's in evidence.

THE COURT: Right. But you're saying three years ago claim construction. Those things are not part of the trial.

MR. SUKDUANG: I'm talking about claim construction in this case on dry powder inhaler. Remember there was a dispute -- the question was the claim construction decision is not part of -- the claim construction decision is not part of the trial. You are correct. But the claim construction and the briefing is

part of the record. And UTC made arguments with respect to dry powder inhaler pointing to the very provisions of the '327 patent acknowledging that it was all out there. We believe Claim 14 is obvious.

For Claim 5, we talked about Saggar. You asked me some questions about that and we put that in the briefing.

For Claim 6, it's exacerbations of interstitial lung disease. Dr. Hill said if a patient is getting better, there's no exacerbation. And further, the six-minute walk distance, which is in Faria-Urbina, in Saggar, those are evidence that Dr. Channick recognized show a -- such a weird way to say it, but a lessening of the worsening. So they're not getting worse. Exacerbation is getting worse, and you're trying to reduce that.

For Claim 9, again, Saggar discloses FVC. It discloses the same magnitude of difference with respect to the INCREASE trial. And Dr. Wertheim actually provided pertinent testimony, although in the context of written description, that deals with obviousness. Dr. Wertheim pointed to the absolute FVC data in the '327 patent and talked about the 1 percent magnitude of difference. It wasn't statistically significant, but he said you start seeing a trend positively that leads to an expectation that you would get statistical significance for absolute because

it was asked by counsel. Let's assume Claim 9 covers both absolute and percent predicted.

For secondary considerations, Dr. Nathan had a list of those things. They all really boil down to the six, seven deadly studies.

THE COURT: I noticed that.

MR. SUKDUANG: A couple of points on that. One, you have to -- for any secondary consideration, it has to be the claims of the patent compared to the closest prior art. He did not compare the claims of the patent to Faria-Urbina, Agarwal -- excuse me. Faria-Urbina, '793, or Saggar. He didn't discuss Agarwal and Parikh. He only compared them to non-treprostinil, non-inhaled drugs. There's no nexus.

With respect to secondary consideration of skepticism, doctors continued to do this. And as we talked about with expectation of success and motivation, the papers disclose the motivation and expectation to do this. There wasn't skepticism.

With respect to --

THE COURT: It would be fair to say based on the evidence that I heard at this trial that the topic was controversial?

MR. SUKDUANG: It depends on who you're talking to.

THE COURT: That would be sort of the definition

of controversy.

MR. SUKDUANG: And I think Dr. Waxman summed it up, actually summed it up, and he was a little bit flippant in his answer and I'm not trying to be flippant with you. But he was asked questions about the riociguat trial, which Dr. Nathan was a part of. He was asked: Did that stop you from using Tyvaso in PH-ILD patients? And he said no. And he was asked why. And he said, "Well, there are some very narrow-minded clinicians out there that if you do anything that's not on the label, you are wrong."

It's a little bit -- and I'm trying -- but that's the plain matter-of-fact statement that those things -- those studies did not dissuade individuals from moving forward.

THE COURT: One thing I thought I heard early in the case but then later on I started to think maybe I misheard or misunderstood. Riociguat, what's the active ingredient in that?

MR. SUKDUANG: Riociguat is the active ingredient and the trial is called RISE-IIP.

THE COURT: Trial called -- riociguat, that is not some form of treprostinil?

MR. SUKDUANG: It is not.

THE COURT: Okay. Thank you.

MR. SUKDUANG: And I believe it's oral as well.

And in terms of secondary considerations, again, the nexus, the '793 is the nexus. UTC argued that to the PTAB. That's earlier issued. The '327 patent cannot be the nexus with respect to any objective indicia. UTC beats this constant drum about these failed studies. We talked about that.

The other argument with respect to obviousness is that Faria-Urbina and Saggar were not actually PH-ILD patients. They were PAH patients. That's what Dr. Nathan testified to yesterday and today. And he said in order to determine whether someone is a PH-ILD, you need right-heart catheterization and high-resolution CT scans. And you need to look at both and you need to look at the scans to make a diagnosis.

Dr. Nathan testified based -- just looking at a paper with no scans that none of these patients were PH-ILD. And he agreed he was making a retrospective diagnosis on a paper. He cannot say that they were wrong in their diagnosis without having the evidence.

And when you look at Faria-Urbina and Saggar, and when Mr. Davies took Dr. Nathan to it, those -- both of those references say there was right-heart catheterization, there was higher resolution CT, and both references say both were looked at to make a diagnosis.

They're not disclosed in the paper, of course,

because they're giant, high-resolution images. Dr. Nathan tried to present some images to you, and they -- one diseased lung. You said, Is that a healthy lung? He said, No, that's a diseased lung so these -- so these images printed don't make any difference.

The fact of the matter is, Dr. Waxman, who was a member of the INCREASE study, knows how to diagnose. He had these data that Dr. Nathan said. He looked at them when making the diagnosis. A retrospective study is not looking back and making a rediagnosis. It's looking at the patients who were diagnosed, treated prospectively, as everybody said in these papers were, and then you have data and then they look at, well, what does this data teach us.

Even though I wasn't running a clinical trial, what did I learn from this? That's a retrospective study. And Dr. Thisted drew this barn and he said -- and I think my counsel called it the --

THE COURT: We don't need to talk about Dr. Thisted.

MR. SUKDUANG: Sure.

With respect to the PH-ILD patients, we believe they're PH-ILD patients. There's no evidence to establish they were not.

And then Dr. Waxman testified that, Are the patients in Faria-Urbina the same as INCREASE? UTC asked

him that. He said, Pretty much the same. That's enough for obviousness.

Finally, on page 888 -- 881 of the transcript from yesterday, Dr. Nathan was asked: "What does it take to do a Phase 3 clinical trial? What would a company need?"

And he said this on page 881, line --

THE COURT: I kind of remember a long answer.

MR. SUKDUANG: It's a very short answer, this part. He said they need -- the question was long. The answer is: "They need some kind of pilot data or proof of concept that they have a shot at a successful clinical trial." That was his answer. Pilot data, proof of concept.

Dr. Nathan and UTC believes Faria-Urbina, '793, Saggar are not pilot studies and are not proof of concept. We disagree. If you take Dr. Nathan as true, UTC conducted a clinical trial that was tens of millions of dollars based on zero evidence and just on a hunch.

Dr. Nathan said that would never ever happen. And Dr. Nathan never pointed to any document that disclosed treprostinil in an inhaled route in PH-ILD except for the prior art that we asserted. Everything he pointed to were drugs of a different context.

THE COURT: The Federal Circuit has said, I think, in various contexts, that the fact that a clinical trial happened doesn't prove either reasonable expectation

of success or motivation to combine.

MR. SUKDUANG: I believe there are cases that say if you run a clinical trial, that might not be enough for reasonable expectation of success or motivation to combine.

But what UTC is saying is that here they're saying the exact opposite. They're saying you cannot have a motivation or a reasonable expectation of success without a Phase 3 clinical trial. That was the very last piece of testimony -- or in the middle of cross-examination for Dr. Nathan.

Mr. Davies asked him --

THE COURT: So that's pretty much a -- I mean, that's practically a legal question. And I did hear Dr. Nathan say that. And I think he's -- you know, he said in this specific case, that's the way it shook out.

MR. SUKDUANG: Correct.

THE COURT: So he wasn't making a general principle statement. But I don't expect him to spend a lot of time reading Federal Circuit cases.

MR. SUKDUANG: No. But here, Your Honor, all you're required to have is a motivation and an expectation of success. We're looking at the prior art that is not around the subject matter, and the subject matter is here.

We're looking at prior art that is the subject

matter. Dr. Nathan admitted the dosing is the same in Faria-Urbina. He admitted that it's Tyvaso.

His dispute is whether it's PH-ILD or not. But he admitted that the data is the data. The six-minute walk data for exercise capacity is there. The data in Saggar was there. He's not disputing that the data is there.

The fight is whether these are PAH patients or not or PH-ILD patients or not. And looking at the string of evidence in this area, there's ample motivation and expectation to render the claims invalid.

I'd like to move on because I don't want to take up more than I need.

THE COURT: Yeah, and I want to make sure just because I would like to be over by 1:00 and --

MR. SUKDUANG: Yes, I apologize.

THE COURT: Sorry about that.

So try to wrap up pretty quickly.

MR. SUKDUANG: Two more topics and I'll keep it short.

THE COURT: Keep it short.

MR. SUKDUANG: Prior sale. I'm going to talk about Claims 1 and 17, Your Honor.

The record is clear. Tyvaso was sold as of 2009. The record is clear. Doctors treated PH-ILD patients with Tyvaso. The record is clear. They used the dosing on

the 2009 label. They went up to 12 breaths. The record was clear on that. And they observed improvements in the exercise capacity, both by six-minute walk and observational data.

There was a sale of the drug. Dr. Saggar and Dr. Hill testified that they had rejections of Tyvaso in this patient population and that they had to write appeals to get those prescriptions approved. Dr. Nathan went into more detail than Dr. Saggar, but Dr. Nathan testified -- excuse me, Dr. Hill.

THE COURT: I remember that.

MR. SUKDUANG: Yes. But he'd write a prescription, it'd get rejected. Even though PAH was on there, it still got rejected because it was a ILD patient as well.

Under Dr. Nathan's opinion, if it said PAH, there should be no rejection because it's approved for that indication. But the fact that prescriptions were rejected shows that doctors were writing scripts, insurance companies knew it and, ultimately, approved it because the doctors convinced them that this was the correct drug for this patient population.

UTC's counter to the actual commercial sale is, one, it's not public. Prescribing information is private. Prior sale does not require a public sale. That's the

Helsinn case from the Supreme Court.

They argued second that UTC did not make the sale. Prior sale doesn't require UTC's commercial sale. It just requires a commercial sale. And Tyvaso was never sold by UTC directly to patients. It's always through the specialty pharmacy.

THE COURT: Right. So I think that's the law, that the pharmacy making a sale counts as a sale --

MR. SUKDUANG: Correct.

THE COURT: -- but that would be a good thing to have a case citation in your brief.

MR. SUKDUANG: Yes.

There's a commercial sale. It doesn't need to be public. It doesn't need to be UTC. Dr. Nathan agreed that it was on sale since 2009. And the record is --

THE COURT: So one other question I have about the commercial sale is really for both of you.

Is -- let's say the pharmacy is making the sale. The sale by itself is not practicing the method. Does -- is there a law that says -- because I never had this come up before -- that a commercial sale -- what's required if there's a commercial sale of something which is a commercial sale and then -- and where there's a prescription written and then a doctor goes off and treats PH-ILD with it?

What's needed to connect those two things that

will make that an anticipatory commercial sale?

MR. SUKDUANG: Sure. So for the commercial sale prong of prior sale, there just needs to be a sale of the device or product, in this case Tyvaso, that would lead to the method. And we have cases. And I apologize --

THE COURT: So that's one other thing, that it will be useful to have a case. And that's something I don't know. So if that's an issue, and it didn't seem to be an issue the way the parties treated it at trial, but sometimes I think of issues that are not issues, I would like to have a case that says what you just said.

MR. SUKDUANG: And then the tying together part of your question.

In the prior sale context, if it's a method, just selling the product, you're right, doesn't practice the method, it's just the product that you use to do it. And there are cases out there that that happened and nothing else happened and that that was enough for the commercial prong.

Here, we have additional steps, as you pointed out. The first step was that there was a prescription for the intended use.

THE COURT: Let's skip over to -- what's the last topic that you wanted to address?

MR. SUKDUANG: Do you want me to cover ready for

patenting on the prior --

THE COURT: No, I'm not really interested in that.

MR. SUKDUANG: Sure. The last issue I want to cover, Your Honor, is what we briefed earlier. And this is the -- we don't believe validity needs to be addressed at all with respect to the pending claims.

Dr. Nathan's testimony is clear. He testified -- I'll summarize without the slide.

Dr. Nathan testified that the claims are directed to the intended result of practicing the method of Claim 1. He testified that you do not need to measure any element in 5, 6, 9, or 17 for infringement. And Mr. Carsten recognized that on infringement.

He testified that if you infringe Claim 1, you automatically infringe the dependent claims. That means there's nothing in those dependent claims that you need to do to infringe. If that's the case, then under the law, and we'll brief this, the claims are directed to an intended result of Claim 1. And that's what he said clearly and unambiguously.

If they're directed to an intended result and you don't need to do anything for infringement, they're not entitled to patentable weight, and therefore, if Claim 1 is invalid, those claims are also invalid because they cannot

be rested upon for patentable weight to try to avoid invalidity if Claim 1 is found invalid.

THE COURT: So it's interesting that you bring that up because the format of these claims, at least some of them, have bugged me since I first learned about them.

But my question is: Isn't this a claim construction issue that should have been brought up long ago?

MR. SUKDUANG: No, Your Honor. Because regardless of the construction, Dr. Nathan is taking the view -- and again, his position is --

THE COURT: But he's interpreting the claims.

MR. SUKDUANG: And he's interpreting the claims in order to assess infringement and validity. That is UTC's position. And if you take their position as true for infringement, for infringement, that you don't need to do any of these things, and that's the only way they can win, because, as I went over, it's not done.

They can only win by saying you don't need to measure these outcomes, you just know they happen. If that is their position on infringement, they cannot, as Dr. Nathan tries to do, say that you need to prove each of these elements for invalidity, that you need to show with concrete proof.

That is not a claim construction issue. That's

a different interpretation of invalidity and infringement. Not a burden issue either, not a preponderance or clear and convincing. It's simply, what do I need to prove for the claim? We understand our burden and they understand theirs.

If you adopt Dr. Nathan's position on infringement, those claims cannot be used to keep the patent valid for validity because you can't have it both ways. You can't have a dependent claim --

THE COURT: All right. I get what you're arguing here. It's something that's going to be briefed so I don't think it's helpful to keep talking about it. And I want to make sure that I give Mr. Carsten enough time. So thank you.

MR. SUKDUANG: Thank you, Your Honor. I appreciate the time and Liquidia appreciates your time.

THE COURT: All right. And, Mr. Carsten, don't feel obligated because I know I said I want to end at 1:00. I don't want to cheat you out of a fair response.

MR. CARSTEN: I'll try my best, Judge, although I'll say I was little nervous when you did say that.

I'm happy to pick up wherever Your Honor would like. I guess on that last point I think, candidly, that that's an issue that will come up in the context of post-trial briefing.

But I would just say on that point briefly, we

rely upon the INCREASE trial to demonstrate as evidence for infringement purposes that these therapeutic effects are happening and are more likely than not to happen. And that's a different sentiment in kind from what we've heard the argument, which was that they have no patentable weight and they don't matter.

It's a very different aspect. And I think, you know, the law is pretty clear that you can meet your burden on infringement by pointing to evidence -- by a preponderance of the evidence and they have to prove their invalidity positions by clear and convincing. And so I think that's where the difference lies here. Same construction, same material, but it's a different analysis for infringement than invalidity.

But I think that will be briefed in the context of the post-trial briefing.

THE COURT: I'm satisfied with that.

MR. CARSTEN: Thank you, Your Honor.

I think I'd like to start where you spent the bulk of your time with Mr. Sukduang, if I may, and that's on the obviousness case.

THE COURT: I think he spent the bulk of his time on it.

MR. CARSTEN: Your time together, shall I say.

THE COURT: Fair enough.

MR. CARSTEN: Mr. Smith, could I have the slide PDX 8.10. And I'll pick it up with, I think, the simple punch line, and that is that the '793 patent, which is instrumental to each and every one of the combinations that Your Honor heard about for every of the six claims, is not prior art.

THE COURT: Well, I mean, if that turns out to be true, yeah, then that's all gone.

MR. CARSTEN: Right. And so it is case dispositive for Claim 14. And in terms of whether or not the patent -- the '793 patent is prior art under 102(a)(1), the effective filing date, the priority date, is April 17 --

THE COURT: So I don't think it's worthwhile to argue this now because I'm going to -- I'm not going to grant your motion today or any time until I've got this briefed. So why don't you go on to assuming that it is actually prior art.

MR. CARSTEN: Okay. Assuming that it is prior art, then, the combination here makes little sense. Mr. Sukduang did his best to sort of provide a rationale for why these would be combined.

But really what you have is Faria-Urbina, which is a nebulized liquid inhaled product. They say, I'm going to take that and its method and then I'm going to combine it with a disclosure that has to do with hemodynamic data, that

has the disclosure for a dry powder in the claims, and then I'm going to combine those to make a new product which is a dry powder product and I'm going to expect that the results of administering that product with the nebulized method is actually going to give me results that are same as or better than an injectable reference from five years prior. It just doesn't add up.

The one thing that the experts did agree upon here is that clinical trials and medicine are unpredictable arts and you do not have an expectation of being able to expect what's going to happen between these various formulations. So when you apply the same chemical compound, the same drug, active ingredient by virtue of these different routes, Dr. Nathan, Dr. Channick, all of them said you can't predict what's going to happen. All you can say for sure is it's not going to be the same.

So that that's the real missing link in terms of this Frankenstein combination of the three references, if you'll have it.

Here's a sample. So Dr. Channick said there are different products and we already talked about this. We can't say one is going to behave the same as the other. It's a different formulation. And we know this based upon the real-world experience of UTC. Remember, UTC had Tyvaso approved in 2009 and then it developed the dry powder

product much later in 2022.

In order to establish that, in order to get that dry powder product approved, the FDA required clinical trials because it wasn't the case that there was --

THE COURT: The requiring -- again, what the FDA said is different than the standard for patentability.

MR. CARSTEN: I agree with you, Your Honor. It certainly is different. The FDA can require things beyond or below a standard for reasonable expectation of success or motivation to combine. I agree with that.

THE COURT: They have to be satisfied -- generally speaking, my impression is the FDA has a much higher standard for approving something than the Patent Office. That's not saying something bad about the Patent Office. It's saying that the standard for patentability often doesn't require any proof that the thing will actually be, among other things, commercially sellable.

MR. CARSTEN: You find -- I guess my point on this, Your Honor, is not about the standards necessarily. But if people skilled in the art, if folks in industry believe that these two different routes of administration would behave the same or would behave similarly, that's inconsistent with requiring additional safety and efficacy data from UTC in order to transfer over to a dry powder product.

I don't want to overstate it. But I do think it's a relevant point and undercuts the positions you're hearing that people would just willy-nilly be motivated these different doses and then expect that an injectable systemic results are going to be obtained but better by virtue of this other inhalation.

That just doesn't make any sense. I think you heard some compelling testimony pointing out that really is not the way that people of ordinary skill in the art would behave in this area.

THE COURT: One of the things that I heard from your opponent that I wasn't thinking about was that Dr. Waxman -- the idea or that argument of the defendant is Dr. Waxman more or less voiced the idea that this is something that should be tried back in 2015. What's your response to that?

MR. CARSTEN: I guess a couple of responses, Your Honor. One, they are not pressing an inventorship defense --

THE COURT: I understand. But in terms of real-world evidence about motivation to combine or reasonable expectation of success, isn't this useful -- isn't Dr. Waxman's thoughts about it useful?

MR. CARSTEN: Well, I think Dr. Waxman -- none of us were in the room between Dr. Waxman and Dr. Rothblatt

at UTC to see exactly what was disclosed and what was shared.

THE COURT: We have evidence in the record of some sort.

MR. CARSTEN: There was a meeting and the evidence in the record that we have is the data from the Faria-Urbina paper. That's Dr. Waxman. He's the lead author. And you heard testimony surrounding that data from both Dr. Thisted and Dr. Nathan suggesting that people of ordinary skill in the art --

Now, mind you, I found Dr. Wertheim really arresting at one point when he came in here and was asked, what did you do to prepare? And he said there's going to be some superstars, the star power in this room is going to be incredible. So I want to read hundreds and hundreds of papers. I want to be as educated as they are.

The people we're hearing from about the off-label use, they were the luminaries. They were the experts in the field. They were not people of ordinary skill in the art.

THE COURT: I assumed Duke and UCLA and Mass General, those are leaders in the field.

MR. CARSTEN: Exactly. So the question is: What did the Faria-Urbina paper teach to people of ordinary skill in the art? And you heard from Dr. Thisted in terms

of the statistical analysis, from Dr. Wertheim in terms of his appreciation for it, and Dr. Nathan that when you actually press into that, there really is no "there" there. Even Dr. Channick admitted that with a low end number that we have in Faria-Urbina, that those things have to be taken with a grain of salt.

And we also know that the Faria-Urbina paper as well as other information that my learned friends have pointed to emphasized the notion -- as well as review articles emphasize the notion that, gee, maybe ILD isn't the right patient profile here. Maybe it's COPD. COPD seems to be better.

And when you look forward and you look at the studies that were actually done, this is a study on treprostinil. It is an inhalation study. It is COPD, which everyone thought or at least seemed to think at the time was the golden child among Group 3. And that failed. That was the PERFECT study.

So I think that the real-world data here, if you're going to look at that, demonstrates -- and I think Dr. Wertheim did a great job of explaining this. I've got seven mountain climbers ahead of me and they all died. That's not exactly motivation to go up and try again. It actually makes it even less obvious to go ahead and try again.

THE COURT: I think in the mountain climbing world, that's extra motivation to go up.

MR. CARSTEN: I would not be a person of skill in the art in that world then. I hope I answered your question. I'm not entirely sure I did.

THE COURT: So we're talking about Dr. Waxman and Faria-Urbina. I guess, I mean, in some ways one of the answers you've given is that the people that the defendant was pointing to as prescribing Tyvaso to PH-ILD patients were -- Judge Connolly has a word for this, but "super POSAs."

MR. CARSTEN: I've heard that.

THE COURT: That may not be his word. But I heard him talk about this, that these people are not persons of ordinary skill in the art. They weren't back at that time and so they're actually the wrong reference group.

MR. CARSTEN: And I think there's a fair bit of that going on here, Judge. It made it seem almost as if everyone in the world was out there prescribing this off label.

THE COURT: I get that, in fact, because I saw a number of places that said it was not widespread. And at the time I was seeing that, I was thinking that's indication it's actually happening.

But in terms of -- and, in fact, I remember

because Dr. Wertheim, who I think said he started in 2014; Dr. Parikh, who was a fellow in 2016, these younger, newer people seem to be -- they seem to say "I'm not really hearing about this," but they were barely POSAs at the time.

MR. CARSTEN: They were POSAs at the time. I think Dr. Wertheim said, yeah, I qualified under either one --

THE COURT: I wasn't sure whether Dr. Parikh was or wasn't.

MR. CARSTEN: I don't recall if he qualified under the parties' --

THE COURT: We don't know enough about his background, I think.

MR. CARSTEN: I think we could find that out for sure and it may actually be in the record.

THE COURT: If it's not in the record, it doesn't count.

MR. CARSTEN: But my point is really the question isn't, what did Dr. Rothblatt extract? Dr. Rothblatt, she's not an M.D., she's not a person of skill in the art. But she spent her life around developing treatments for pulmonary hypertension, so she's quite knowledgeable.

The question is what she derived and whether she was motivated or inspired to carry forward. The question is

who was a person of skill in the art? What was Dr. Wertheim motivated to do based upon Faria-Urbina? And that evidence is crystal clear and that is nothing.

You heard Dr. Wertheim. I wouldn't do it. I prescribed Tyvaso for PAH and PAH only. That was the state of the art. That was the evidence. And why --

THE COURT: Well, that kind of actually makes sense because if you're two years attending physician, whatever, and you prescribe things off label and the patients end up dying, you're probably going to have to get a new job, whereas --

MR. CARSTEN: I think you won't be practicing in three years.

THE COURT: -- whereas the people we've heard from in the trial, the Dr. Channicks and Nathans of the world, you know, they can kill a few people and they're still going to keep on going.

MR. CARSTEN: Yes, Your Honor. But you get my point, I think, and that is --

THE COURT: Not a point that I thought of before you brought it up.

MR. CARSTEN: It's not -- yeah, I think there's been -- we pointed to the seven deadly studies and there have been comments about, well, are they deadly or aren't they, and all this other stuff about them.

You know, I think where I come down on this, where I land on this one, Judge, is, you know, these seven deadly studies, maybe not all of them killed people, but, man, this is a very vulnerable patient population. These are people who are going to die.

THE COURT: Yeah, I've heard that.

MR. CARSTEN: And then, two, even if the -- with RISE-IIP, you heard the story from Dr. Nathan about how he spent the three days in Europe going through CT scan after CT scan trying to figure out what happened here and what caused this problem.

You know, I think if not killing people -- if not deadly in that sense, you've heard about the nihilism that surrounded this. It killed the motivation to climb the mountain further. That's the seven deadly studies.

And so with that, I mean, I think there's no motivation to combine these disparate references and have any expectation that you're going to mirror and better an injectable result.

Remember, the only FVC that went up in this case that you heard about was from the Saggar 2014 paper. Everyone else went down, down, down, and that's bad. And that Saggar reference, the p-value was like .687.

I mean, that's -- and to say, okay, I'm going to start with an inhaled nebulized and then convert it to a dry

powder and expect I'm now going to turn around and get these FVC values that go up, that's outrageous. That's not what a person of skill in the art would expect. That's not what Dr. Wertheim would expect.

And so I don't believe that they've met their burden by clear and convincing evidence on any of these, even assuming that the '793 patent stands, which it ought not.

And as a separate minor measure, I've been doing this a while, not as long as you, Judge, but a while, and I've never --

THE COURT: I hope you haven't been doing it longer than me.

MR. CARSTEN: -- and I've never seen on direct examination somebody point to the '327 patent in order to justify or credit a teaching from the prior art to explain why it's relevant.

You pointed out earlier, Judge, Section 103, which has the manner of the patentee's invention shall not be used to invalidate the patent. We have that expressly. The man looked -- Dr. Channick looked expressly at INCREASE data to justify the importance and relevance of the Saggar 2017 FVC data. I mean, that's expressly using hindsight. No doubt about it.

THE COURT: Whatever it is that you're referring

to, I didn't catch it while it was happening, assuming your memory of it is correct. So to the extent that that's an issue about anything that's occurred in the trial, that's something you should bring up in your briefing.

MR. CARSTEN: Yes, Your Honor, we certainly will.

Just a few moments to go, and I'd like to spend a little bit of time on each of the other three defenses very briefly, if I might.

THE COURT: Yes.

MR. CARSTEN: If we could go, Mr. Smith, to PDX 8.5.

And this is the so-called prior sale defense. I mean, we talked a little bit about this. You remember they had a prior use defense. And then that was stricken because it was waived or it hadn't been raised in a timely manner.

THE COURT: Right.

MR. CARSTEN: And then it was -- what they did, essentially, was repackage that prior use defense. Of the prior sale defense, I would say that 95 percent of the evidence that went in had to do with use, not sale.

THE COURT: Yeah, but the use is related to why the sale might be a commercial sale to --

MR. CARSTEN: I'm not saying that -- if I were trying the case on their side, I probably would have chosen

the same tactic; right? I mean, it makes sense why they chose to introduce the evidence, and it is relevant in some sense, the prior sale, and it gives context there.

I'm not suggesting that anything improper happened, but I am pointing to the quantum of evidence that really has nothing to do with sale, but really is about use. And in order to qualify as a prior sale, you need a commercial sale of the patented here method.

And so Your Honor asked my learned friend a question earlier, what do you do when you have a situation where you have a product and, you know, it's available for -- it's capable of being used in a couple of different ways and you have a patent case?

You asked in the context specifically of ANDAs, and I don't think I have a case in hand for that --

THE COURT: I don't think it would make any difference if it was a non-ANDA.

MR. CARSTEN: I don't think it would, but in the event that it might, I'm going to certainly be scouring the Westlaw for one.

But I do have a case called *BASF*, which says that when you sell a product that can be used for multiple uses and you're not giving guidance or advice on the one use that's claimed, that doesn't count. That's not enough.

Because you -- the question isn't whether you're

selling the product that could be used for that. The question is, are you selling the actual -- something that embodies the method itself? Are you selling the method? And so I think the *BASF* case stands for that proposition, and we're happy to brief that.

But just very briefly on this, we don't think there was evidence of a sale at all in the sense of a clear and convincing level of evidence for a sale.

THE COURT: If I had to say, I think I heard enough evidence to be convinced that there were pharmacies that were filling out Tyvaso prescriptions where the doctors had written them to treat PH-ILD.

I understand there's no specific sale that's been identified, but I just don't think that's necessary given the number of different doctors that I heard who, as we've talked about as "super POSAs," that they were prescribing it for this purpose following the 2009 label dosing regimen and that the patients weren't getting this for free.

So as a factual matter, I think I'm going to find that there were sales. There may be things on the periphery that mean they're not sales that count, but I think there were sales by pharmacies for sure.

MR. CARSTEN: Okay. I understand. And thank you for sharing that. I'm going to do my best to try to

disabuse you of that notion, of course, but perhaps not in the next five minutes.

But I'll say there is record evidence that not every ILD patient had PH. In fact, I think Dr. Channick agreed with me that upon presentation or diagnosis, there's -- quoting a Dr. Nathan paper -- about 8 to 15 percent of patients who were diagnosed with ILD have PH.

So just checking boxes doesn't say, according to the Court's claim construction --

THE COURT: I'm thinking of Dr. Hill who is a person who I'm sure was telling the truth to the best of his ability who said he's done a couple of dozen of these over the years. You know, so even if one patient was misdiagnosed, that's a couple of dozen minus one.

MR. CARSTEN: But he also said that each one of those patients had involved some PAH and that typically he would check the box for PAH on the form that was sent into the insurers.

And so the sale, we submit that there isn't clear and convincing evidence that the sale was for PH-ILD in terms of the transaction. In fact, you heard Dr. Saggar say, yeah, we didn't have much challenge because we would tick the box that said PAH.

And you heard Dr. Waxman saying, yeah, thank goodness when this got approved for PH-ILD, I could put down

the right diagnosis to get this approved.

THE COURT: I think Dr. Waxman also said something about generous payers, which I certainly interpreted to be referring to people who were letting -- reimbursing him for off-label use.

MR. CARSTEN: That's the earnings call with Dr. Rothblatt from UTC. And in that context, she said, thanks to the kindness of generous payers --

THE COURT: He said that somewhere -- I thought he said that. Well, maybe I'm confusing it. I thought Dr. Waxman had actually said that, maybe in his speech to the John Vane Society.

MR. CARSTEN: Well, referring to the Dr. Rothblatt statement, she said, "Thanks to the kindness and generosity of payers, we've been able to -- some Group 3 patients have been able to see benefit."

And so that's not saying that the payment, that the prescription, the reimbursement was specifically for Group 3. It just so happened that maybe it was done under the PAH label and the group -- it was a Group 3 patient who happened to see benefit from that transaction.

And so this is their burden by clear and convincing evidence. I get they've got a number of these super POSAs, to use your term, or whatever you credit it to, who are out there saying they've done it, but in almost

every case or every case that I can recall there was always a suggestion these people had PAH, or at least the insurance company, that the person who was doing the buying, understood it was for PAH.

And so I submit that even if you're going to say, yeah, I'm convinced that there were commercial sales, I think you need to go a step further, and I don't think that they've tied that up with a bow.

I think it could have been something that they could have done with a patient record, with a transaction, with something that clearly established back before April of 2020 that they've actually done it. But that's their burden and they never did. And it's a dearth of documentary evidence there.

Moreover, I think it's -- this is an anticipation flavor. And so when you look at -- remember, they said as of 2009, I started doing this. 2009, the only approved indication was PAH, you've heard that ad infinitum.

But in terms of the dosage, the label says you can -- if three breaths are not tolerated for your first dose, you can reduce to one to two breaths. That means that the approved indication on the label, the approved dosage, was a range from 6 micrograms to 54 micrograms.

That is different than the patent claim which requires at least 15 micrograms up to a maximum tolerated

dose. And under the Court's -- well, this is a little bit inherent anticipation argument. But understanding it's pharmaceuticals, if you're relying upon a method for inherent anticipation and the methods differ, there's no inherent anticipation.

And so --

THE COURT: Sales of pharmaceuticals, I had a --

MR. CARSTEN: I'm citing your case to you, Judge. Yeah, I've done that a fair bit today. I did it with the --

THE COURT: Well, it's hard to say. You know, I had a BASF case, but I don't think it was the BASF case you cited. So the names of these people, particularly in the pharmaceutical field, you know, you see the same names over and over again.

MR. CARSTEN: Understood.

I want to move forward to the clinical -- the DTX 008 anticipation very briefly. I think this falls apart in the same reason, the salient case that I mentioned to you, and that is, you know, Dr. Channick stood up on direct and said, oh, it's the same dosing schedule, and then we walked through it with him and it was not the same dosing schedule as well.

And I also --

THE COURT: So we're talking about protocols

now?

MR. CARSTEN: Yes, the protocol. You call it the protocol. We call it DTX 8. They call it the INCREASE trial. Whatever. We're all talking about the same thing.

THE COURT: Yeah, yeah, yeah, but calling it DTX is the least helpful way of reminding me of what it is. I've got it now.

MR. CARSTEN: Okay. He said, well, it's the same in terms of the dosing schedule. And we walked through it and, no, it was not at all. He admitted, it's not the same dosing schedule. And it's a different patient population.

Now, the testimony that came in seemed to suggest, well, at least Liquidia wants you to say, yeah, this is -- it's a subset of the population that went in and they would have experienced more benefit. But Dr. Channick admitted that on the protocol that was not run, the DTX 8, what they call the protocol, whatever, there is a carbon monoxide diffusion limitation for the pollution criteria. And in INCREASE there was an important FVC limitation where the included patients had to be greater than or equal to 70 percent under FVC. Remember that one big blow and the percent. There's no evidence that people in that -- would have been here would have actually made it into the patient population.

And the one thing we know from a different dosing regimen and a different patient population is unpredictable results. Dr. Channick said it himself. I mean, the differences that we described in direct, with a different patient population, you agree the results would in fact be different from the results observed in the INCREASE trial.

I can't predict the results. They may or may not. I don't think anybody can say that they would have exactly the same results.

So we have a salient situation, which is a different method on a different patient population. And then we've got the uncertainty surrounding what would happen had that hypothetical clinical trial ever got run. And there's no evidence presented on that.

The final point, unless there are questions on this, Judge --

THE COURT: I take it your last point really was just you can run a clinical trial and then rerun it a year later with the exact same protocol dealing with the same centers and you get different results.

MR. CARSTEN: You would get different results, although assuming, we hope, that if there were statistically significant results in that first clinical trial, that those would be reproduced.

THE COURT: But even that is not a guarantee.

MR. CARSTEN: It's not guaranteed. And so -- but that's, you know, 95 percent confidence essentially, right, that's the probability.

THE COURT: So that's the reason why -- I should have ask this to Mr. Sukduang, but that's --

The reason why I'm sort of dubious about all the inherent anticipation is none of this is leading to something that you can say as a scientific matter that it's going to happen. We're not in the world of hard science, we're in the world of probability, statistics, and just randomness.

So I'm pretty dubious on this. So if there's something else you want to say, that would be good.

MR. CARSTEN: Well, I think I'm going to leave that right there, Judge. I'm fine with that.

THE COURT: What else do you have?

MR. CARSTEN: The final point I've got, and I'll be very, very quick about it, is written description. And this pertains to Claim 9.

THE COURT: Right.

MR. CARSTEN: This is sort of a theory of the case, and I think it bears in mind -- it bears to bear in mind over the course of evaluating Liquidia's arguments what they're trying to do is conflate INCREASE with the claim --

with the patent claims themselves and say, essentially, they're one and the same.

And they're not. They are broader than INCREASE and the specification is broader than INCREASE in some ways. And so here is a prime example of that. And I think the absolute FVC, so the same measurement, but expressed in terms of the volume of the blow as opposed to the percent predicted of the blow. You remember the demonstrative; right?

THE COURT: Yes.

MR. CARSTEN: There was no statistical significance on the trial for the ITT, the entire population on that, at weeks 8 or 16.

THE COURT: So do the fact that there were some populations for which there was statistical significance, is that a relevant fact?

MR. CARSTEN: I don't believe so. I mean, the specification at column 2 says that we may run -- in some embodiments you may run trials, you may see statistical significance. The inventors possess the ability to know how to determine statistical significance. They understood the milliliter, volume, and the percent.

THE COURT: In other words, your argument here is in the intent-to-treat population, given that we understand the predicted FVC and absolute FVC, that I think

it's fair to say -- tell me if I'm wrong -- absolute FVC, as you know, the variables about the person and you translate it according to widely understood measures into predicted FVC. They're basically saying that they have the same underlying concept and the predicted FVC was statistically significant in the trial.

MR. CARSTEN: I said it and I think Dr. Wertheim said it yesterday -- maybe yesterday, exactly right. I mean, I think it is one blow and how you describe that is up to you in terms of whether you want to follow those guidelines and express it as percent then here's the demographic in patient who want to express it just as a volume.

THE COURT: And the chart as a whole, but even the chart just for the total population says what to me makes intuitive sense, which is to the extent you're trying to study something, you do want to normalize the data. So the predicted FVC has much better results than the absolute FVC because if you haven't normalized the data, one group could look quite a bit different than the other group in terms of lung capacity.

MR. CARSTEN: When I saw this claim, the first time the jump to mind was a picture of Shaquille O'Neal sitting next to Simone Biles. And that kind of made it -- that clarified for me the difference between the percent

predicted versus the actual milliliters. We've got to somehow compare those two and this is the way that physicians do it.

With that, unless Your Honor has questions, I'd like to thank the Court and thank the court staff for its patience and time.

THE COURT: Thank you. Let me check. I have one or two questions that I've written down that --

MR. CARSTEN: Shall I stay?

THE COURT: So let me check them because sometimes I ask them in the course of -- because they kind of come up in the course of the argument and sometimes they don't or I forget or something else. So I got that one. So actually you can just stand right there.

But, Mr. Sukduang, if you ran the INCREASE trial again using the same protocol, the same centers, and the same investigators but a different 320 people who meet the criteria, would you get the exact same results?

MR. SUKDUANG: Would you get literally the same numbers?

THE COURT: Yes.

MR. SUKDUANG: You couldn't and no one would say you could.

THE COURT: Okay.

MR. SUKDUANG: But you'd get the same

magnitude -- Mr. Carsten said that when you run the INCREASE trial -- and what they want to establish is that if you ran the INCREASE trial again, you would get the same magnitude of effect, and that's really what the FDA looks at.

THE COURT: Maybe you would and maybe you wouldn't. That's the reason why it's -- the results are set as probabilities rather than facts; right?

MR. SUKDUANG: Right. But in terms of if you're asking this question in the context of inherency, you have to go back to your claim. Your question is and we believe -- and under the case law we believe that when you asked Dr. Channick this, you asked me this: If you ran it, would you get the exact same thing? He said no. Dr. Nathan said no. And that's truthful.

But for inherency, the question was not whether you run the INCREASE trial over and over and over again you get the exact results. The question is for inherency, under the law and under this claim, when you run the INCREASE trial, will one or more patient necessarily and inevitably get the result?

THE COURT: I don't think that's probably the right question. In any event, you can brief that.

So I asked, I think, Mr. Sukduang, but I didn't ask you, the correlation between BNP and NT-proBNP, as you stand here right now, do you think how those two are related

was stated with enough -- stated in a way that I could actually conclude that one is a proxy for the other?

MR. CARSTEN. No. I don't believe so at all, Your Honor. In fact, on infringement I asked Dr. Channick and he said, "I don't even measure NT-proBNP. I measure BNP" as if they were different. And when it came up on his direct for invalidity, he said, "Well, NT-proBNP is a fragment of BNP."

THE COURT: That was the word.

MR. CARSTEN: And I don't think there was ever any record evidence introduced to establish that they were related in any kind of linear way or how you would say that if you see an increase or decrease on one, it would translate to the other. All we have is these are different and they're somehow related. And I don't think that's enough.

THE COURT: So that's something I'm interested in. I think I asked Mr. Sukduang to brief it and pretty much -- if I ask one of you to brief something, I'm expecting both of you to brief it. But I am interested in this question.

MR. CARSTEN: Thank you, Your Honor.

THE COURT: Okay. I think that's it. Let's just try to wrap up one more thing and then we'll all have lunch.

What about -- I think I told you I wanted a fairly expedited schedule for briefing this. What do you think in terms of -- do you have a way of dividing up when these briefs would be due? I think I said I would like to have them all in a month, I think.

MR. CARSTEN: Your Honor, we talked during the break before closings and we've agreed on page limits. But we have a different view in terms of the schedule.

THE COURT: Why don't you tell me what the page limits are and see how much I agree with you.

MR. CARSTEN: We agreed -- like our last case, we agreed on a hundred pages split between the opening and the second round. And they would go first on validity and we would go first on infringement.

THE COURT: So this hundred includes the infringement and validity?

MR. CARSTEN: Both. And parties can split them however they want.

THE COURT: Right, because I think infringement is going to take a lot less pages than invalidity. So a hundred pages altogether?

MR. CARSTEN: Combined.

THE COURT: Better. Okay. Thank you.

MR. CARSTEN: You have enough to read in this case, Judge.

THE COURT: And the way it would work is you're going to submit three briefs or two briefs?

MR. CARSTEN: We're thinking three and ten pages for the reply.

THE COURT: That's in addition to the hundred?

MR. CARSTEN: 100 pages for the two and then a ten-page reply.

THE COURT: So because you would -- a hundred pages for the two is you will submit something on infringement and we'll say that's 25. And then they will submit something on invalidity and then your response to their invalidity would be up to 75. Is that what you're saying?

MR. CARSTEN: Yes, exactly.

THE COURT: That's what I allowed you all three years ago?

MR. CARSTEN: It is.

THE COURT: Okay. Then ten pages for reply. All right.

MR. CARSTEN: Then, Your Honor, we're sort of hot to trot on this 52(c) issue, as you might imagine. We had hoped that we might be able to convince you that we could get an expedited briefing schedule and -- because whether or not obviousness is going to be briefed in the post-trial briefing, that would change the allocation of

pages dramatically.

What we had hoped we would be -- we would get you expedited briefing on the 52(c) motion and we would say that we're either going to file these documents, the first round of post-trial briefing, two weeks from today or three days after you issue a ruling on 52(c).

THE COURT: I have to tell you my reaction to the 52(c) is like you want a preliminary injunction and long ago that route was pursued. And I'm not really inclined to be saying, okay, plaintiff says you can decide this easily, Judge. Let's break it out and you have do that first and we'll see how that goes before we get on to the next thing.

So the only reason you're asking for it is because they were on the market and that's because the court in North Carolina denied your motion there, so I think they're on the market. And if I rule in your favor on this, it's going to be a mess regardless. So I'm not real inclined to break it out and do -- so in this briefing on invalidity that is to come, do you want to -- so I think to the extent that you made the motion, denying that but, obviously, without any prejudice to you bringing it up, so I think you ought to include that -- you ought to address that in your briefing in this hundred pages.

MR. CARSTEN: Okay.

THE COURT: And presumably, Mr. Sukduang, since

you're going first on invalidity, you probably ought to address it in the opening brief; right?

MR. SUKDUANG: Of course.

THE COURT: Okay. All right. So you said the schedule two weeks from now is probably -- so I think I said a month today is June 26th probably. So we're talking July 26th. How do you want to break this up?

MR. SUKDUANG: Can I ask one thing, Your Honor? The Fourth of July holiday is next week and I think both teams have been here nearly two weeks. I understand you asked for a month. Could it be five weeks just because of the holiday and everybody has been gone from their respective individuals at home?

THE COURT: So you're appealing to my goodwill as a human being here?

MR. SUKDUANG: You can ask any of my associates that I'm like, let's burn this out. But I understand that I need to be kind and I do have some personal matters I need to address that I talked about before.

THE COURT: So instead of -- okay. One week.

MR. SUKDUANG: With that, Your Honor, I think given, essentially, five weeks, I'm pretty sure come Monday we'll be able to do a split for that and get that back to you Monday or Tuesday. Given that it's five weeks, I don't think there's going to be much dispute in terms of timing.

MR. CARSTEN: I think our proposal is two weeks, two weeks, and a week.

THE COURT: Two weeks, two weeks, and a week and two weeks starts from today. And I think I said something about getting in any corrections to the transcript. I think we -- so you need to do that. Today is Thursday. You need to do that ASAP so you're working with the actual transcript and will -- sometimes it changes page numbers, which is irritating. So get them in and just in case or to save effort here, when the transcript -- if the transcript reflects somebody misspeaking, that's the way it goes. You all misspeak. So don't try to correct it to what you wish had been said.

But if there is -- and I'm sure there is because we're all human. If there are -- and there was a lot of large, complicated words being dropped that everybody was having trouble with, if they're that kind of stuff, get that in because -- get it in as soon as you can. Okay?

MR. CARSTEN: Will do. And, Your Honor, just housekeeping measure, you typically like to get hyperlinked materials. So can we do that maybe a week or two after?

THE COURT: It's got to be sooner than that. While you're doing the reply brief, you can designate someone to be lining up the hyperlink briefs. You can hyperlink the opening briefs and answering briefs before.

Why don't you say the first two sets of briefs ought to be in by whenever the reply brief is due.

MR. SUKDUANG: Hyperlink version?

THE COURT: Yes.

MR. CARSTEN: I just got a thumbs up from the real person who's doing the work and she said yes.

THE COURT: That's the smiling woman there.

MR. CARSTEN: The one next to the smiling woman, she's doing the work.

THE COURT: Now we know why she's smiling. Okay. That would be good and get the reply brief hyperlinked in soon thereafter, but that would be good. Okay?

MR. SUKDUANG: On the corrections of the transcripts, should we be using the dailies that you sent or will there be an official transcript --

THE COURT: Why don't you all talk about that after I'm done, all right?

So we're done. Thank you very much for your cooperation in the actual conduct of the trial and we'll be in recess.

C E R T I F I C A T E

I, Deanna L. Warner, a Registered Professional Reporter, do hereby certify that as such Registered Professional Reporter, I was present at and reported in Stenotype shorthand the above and foregoing proceedings.

Deanna L. Warner, RPR, CSR
Official Court Reporter
U.S. District Court

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